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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 382

Federal Aviation Administration

14 CFR Parts 1, 11, 121, 125, and 135

[Docket No.: FAA–2014–0554; Amdt. Nos. 1–69; 11–60; 121–374, 125–65, 135–133]

RIN 2120–AK32

Acceptance Criteria for Portable Oxygen Concentrators Used on Board Aircraft; Correction

AGENCY: Federal Aviation Administration (FAA) and the Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule which replaces the existing process by which the Federal Aviation Administration (Agency or FAA) approves portable oxygen concentrators (POC) for use on board aircraft in air carrier operations, commercial operations, and certain other operations using large aircraft. The FAA currently assesses each POC make and model on a case-by-case basis and if the FAA determines that a particular POC is safe for use on board an aircraft, the FAA conducts rulemaking to identify the specific POC model in an FAA regulation. The final rule replaces the current process and allows passengers to use a POC on board an aircraft if the POC satisfies certain acceptance criteria and bears a label indicating conformance with the acceptance criteria. The labeling requirement only affects POCs intended for use on board aircraft that were not previously approved for use on aircraft by the FAA. Additionally, the rulemaking will eliminate redundant operational requirements and paperwork requirements related to the physician's statement. As a result, the rulemaking will reduce burdens for POC manufacturers, passengers who use POCs while traveling, and affected aircraft operators. The final rule also made conforming amendments to the Department of Transportation's (Department or DOT) rule implementing the Air Carrier Access Act (ACAA) to require carriers to accept all POC models that meet FAA acceptance criteria as detailed in this rule.

DATES: This correction will become effective on July 5, 2016.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact DK Deaderick, 121 Air Carrier Operations Branch, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, AFS–220, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–7480; email *dk.deaderick@faa.gov.* For questions regarding the Department's disability regulation (14 CFR part 382), contact Clereece Kroha, Senior Attorney, Office of Aviation Enforcement and Proceedings, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9041; email *clereece.kroha@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

On May 24, 2016, the FAA published a final rule entitled, "Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft" (81 FR 33098).

The final rule affects the use of POCs on board aircraft in operations conducted under title 14 of the Code of Federal Regulations (14 CFR) parts 121, 125, and 135, by replacing the existing FAA case-by-case approval process for each make and model of POC in Special Federal Aviation Regulation (SFAR) No. 106, with FAA acceptance criteria. Under SFAR No. 106, each time the FAA approves a specific model of POC for use on board aircraft, the agency updates the list of approved POCs in the SFAR.

The final rule removes SFAR No. 106 and replaces it with POC acceptance criteria and specific labeling requirements to identify POCs that conform to the acceptance criteria. POCs that conform to the final rule acceptance criteria will be allowed on board aircraft without additional FAA review and rulemaking.

As with existing requirements for FAA approval of POCs that may be used on aircraft, the final rule acceptance criteria and labeling requirement only apply to POCs intended for use on board aircraft.

However, the final rule was published with an incorrect references to AC 120–95B, when the new AC is actually AC 120–95A.

Correction

In FR Doc. 2016–11908, pages 33102, 33111, and 33113, in the **Federal Register** of May 24, 2016, make the following corrections:

1. On page 33102, third column, footnote 5, first line, correct "AC 120–95B" to "AC 120–95";

2. On page 33111, in the first column, tenth line from the bottom, correct "AC 120–95B" to read as "AC 120–95A";

3. On page 33113, in the first column, third line from the top in parenthesis, correct "AC 120–95B" to read as "AC 120–95A";

4. On page 33113, in the second column, second paragraph, thirteenth line, correct "AC 120–95B" to read as "AC 120–95A".

Issued under authority provided by 49 U.S.C. 106(f) in Washington, DC, on June 23, 2016.

Dale A. Bouffiou,

Acting Director, Office of Rulemaking.

[FR Doc. 2016–15770 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 13 and 406

[Docket No. FAA–2016–7004; Amdt. Nos. 13–38, 406–10]

RIN 2120–AK90

Revisions to the Civil Penalty Inflation Adjustment Tables

AGENCY: Federal Aviation Administration, DOT.

ACTION: Interim final rule.

SUMMARY: This interim final rule is the catch-up inflation adjustment to civil penalty amounts that may be imposed

for violations of Federal Aviation Administration regulations, as required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: These amendments become effective August 5, 2016.

FOR FURTHER INFORMATION CONTACT: Cole R. Milliard, Attorney, Office of the Chief Counsel, Enforcement Division, AGC–300, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3452; email *Cole.Milliard@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking and Applicable Statutes

The Federal Aviation Administration (FAA's) authority to issue rules on aviation safety is found in title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. The Secretary of Transportation's authority to regulate the transportation of hazardous materials ("hazmat") by air is in chapter 51 of title 49; civil penalty authority is in section 5123. The Secretary's authority to regulate commercial space transportation may be found at 51 U.S.C. subtitle V, sections 50901–50923 (chapter 509), which provides for the Department of Transportation (DOT), and, through delegation, the FAA to impose civil penalties on persons who violate chapter 509, a regulation issued under chapter 509, or any term or condition of a license or permit issued or transferred under chapter 509. 51 U.S.C. 50906(h)–(i), 50917.

This rule implements the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), Public Law (Pub. L.) 101–410, as amended by the Debt Collection Improvement Act (DCIA) of 1996, Public Law 104–134, and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act), Public Law 114–74, codified at 28 U.S.C. 2461 note.

The FCPIAA, DCIA, and the 2015 Act require Federal agencies to adjust minimum and maximum civil penalty amounts for inflation to preserve their deterrent impact. The 2015 Act amended the formula and frequency of inflation adjustments. It requires an initial catch-up adjustment in the form of an interim final rule, followed by annual adjustments of penalty amounts. The amount of the adjustment must be made using a strict statutory formula discussed in more detail below.

Background

The FCPIAA determines inflationary adjustments by increasing civil penalties by a cost-of-living adjustment (COLA). Under the FCPIAA, as amended by the 2015 Act, the COLA for each civil penalty is normally the percent change between the U.S. Department of Labor's Consumer Price Index for all-urban consumers (CPI–U) for the month of October of the calendar year preceding the adjustment and the CPI–U for the month of October of the previous calendar year.

However, under the 2015 Act, the FAA must first use a different "catch-up adjustment" formula. To determine the amount of the catch-up, it must use the percent change between the CPI–U from the October of the calendar year in which the penalty was last set or adjusted by statute or regulation other than by inflation adjustments under the FCPIAA and the CPI–U from the October preceding the adjustment. The increase must be rounded to the nearest $1, and can be no greater than 150% of the penalty levels in effect on the date of the 2015 Act's enactment, which was November 2, 2015.

Method of Calculation

The 2015 Act directed the Office of Management and Budget (OMB) to issue guidance on implementing the inflation adjustments required by the 2015 Act no later than February 29, 2016.[1] On February 24, 2016, the OMB released this required guidance, which contains complete instructions on how to calculate the catch-up adjustment.[2] An agency calculates the catch-up adjustment by multiplying the maximum or minimum penalty amount by a multiplier calculated based on the year the penalty was last set or adjusted by Congress or rulemaking (other than inflation adjustments under the FCPIAA). As examples, here are how the adjustments for 49 U.S.C. 5123(a)(1) (hazmat) and 51 U.S.C. 50917 (commercial space) were calculated:

(1) Find the multiplier listed in the OMB guidance for the year the penalty was last set or reset.

Section 5123 was last adjusted in 2012, so the multiplier is 1.02819.

Section 50917 was last set in 1984, so the multiplier is 2.25867.

(2) Multiply the penalty amount by the multiplier, and round to the nearest dollar.

$75,000 * 1.02819 = $77,114
$100,000 * 2.25867 = $225,867

(3) Multiply the 2015 penalty amount (including any prior adjustments under the Inflation Adjustment Act) by 2.5,[3] and round to the nearest dollar to find the 150% cap for the catch-up adjustment.

$75,000 * 2.5 = $187,500
$120,000 * 2.5 = $300,000

(4) Compare the dollar amount from (3) to the dollar amount in (2). If (2) < (3), (2) is below the 150% cap and is the adjusted penalty. If (2) > (3), the 150% cap is applied and becomes the adjusted penalty.

$77,114 < $187,500. Therefore, $77,114 is the adjusted penalty.

$225,867 < $300,000. Therefore, $225,867 is the adjusted penalty.

The following chart shows the values used in the calculations and the rounded catch-up adjustment. All of the penalty adjustments fell below the 150% cap on the catch-up adjustment:

49 U.S.C. Statute	Year last set/adjusted	Penalty when last set/adjusted	Multiplier from OMB	Catch-up adjustment
5123(a)(1)	2012	$75,000	1.02819	$77,114
5123(a)(2)	2012	175,000	1.02819	179,933
5123(a)(3)	2005	* 450	1.19397	537
5123(a)(3)	2012	** 75,000	1.02819	77,114
46301(a)(1)	2003	25,000	1.28561	32,140
46301(a)(1)	2003	1,100	1.28561	1,414
46301(a)(3)[4]	N/A	N/A	N/A	N/A

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[1] 28 U.S.C. 2461 note.

[2] OMB Memorandum M–16–06.

[3] It is 2.5 rather than 1.5 because the cap is described in terms of the amount of the *increase;* that is, the amount added to the penalty as a catch-up cannot be greater than 150% of the penalty, rather than being limited to 150% of the penalty itself. 28 U.S.C. 2461 note ("The amount of the increase in a civil monetary penalty . . . shall not exceed 150 percent of the amount of that civil monetary penalty on the date of enactment"). Thus, the cap is $x + 1.5x = 2.5x$, where x is the penalty amount.

49 U.S.C. Statute	Year last set/adjusted	Penalty when last set/adjusted	Multiplier from OMB	Catch-up adjustment
46301(a)(5)	2003	10,000	1.28561	12,856
46301(b)	1987	2,000	2.06278	4,126
46302	1984	10,000	2.25867	22,587
46318	2000	25,000	1.36689	34,172
46319	2003	10,000	1.28561	12,856
47531 [5]	N/A	N/A	N/A	N/A
51 U.S.C. 50917 [6]	1984	100,000	2.25867	225,867

* Minimum.
** Maximum.

Provision for Reduced Catch-Up Adjustment

The 2015 Act allows an agency to request that a catch-up adjustment be lower than what is calculated using the 2015 Act's formula. This requires a determination by the head of the agency, following a notice of proposed rulemaking, opportunity for comment, and a final rule, that the catch-up adjustment will have a negative economic impact or has social costs that outweigh the benefits. In addition, the director of OMB must concur with the agency head's determination as the adjustment is an economic transfer. The Administrator of the FAA does not believe that any of the catch-up adjustments in this rule will have a negative economic impact or have social costs that outweigh their benefits.

Amendments to Subpart H of 14 CFR Part 13

The FAA codified the statutory formula for inflation adjustments under the FCPIAA and DCIA in subpart H of 14 CFR part 13. Rather than amending the subpart to match the 2015 Act, paragraphs (a)–(c) of § 13.305 containing the formula are being deleted as unnecessarily duplicative of the statute. Section 13.303 is also being deleted because it duplicates definitions of terms given in the statute. Section 13.301(a) is being amended to include a reference to the 2015 Act.

Amendment to Section 406.9(a)

The current version of 14 CFR 406.9(a) states the maximum civil penalty that can be imposed under its authority "as adjusted for inflation." This clause is being deleted as redundant and unnecessary. The maximum penalty amount as amended by this rule will already be adjusted for inflation, as will the future annual adjustments required by the 2015 Act. Retaining this clause could also create a false impression that the penalty amount is adjusted for inflation other than by the 2015 Act. Therefore, the "as adjusted for inflation" clause is being removed.

Good Cause for Not Having Notice and Comment

Under the Administrative Procedure Act, 5 U.S.C. 553(b)(B), a final rule may be issued without public notice and comment if the agency finds good cause that notice and comment are impracticable, unnecessary, or contrary to public interest. Good cause exists in this case to dispense with public notice and comment because adjustments to civil penalties for inflation are required by Congress, as set forth in Section 5 of the FCPIAA, as amended, in order to maintain the deterrent effect of civil penalties and promote compliance with the law. As the Administrator of the FAA has determined that none of the catch-up adjustments should be lowered due to negative economic impact or social costs that outweigh benefits, there is no place where the FAA might apply discretion or policy judgments in calculating the adjustments. The formula for determining the adjustments is laid out by statute and cannot be amended by the FAA, even in response to public comment. Accordingly, public comment is unnecessary in this case.

Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows.

This rule adjusts for inflation to civil penalties for violations of aviation safety, hazmat, and commercial space provisions in accord with the Federal Civil Penalties Inflation Adjustment Act Improvement Act (the 2015 Act), Public Law 114–74, Section 701 (November 2, 2015). The Director of OMB provided guidance to agencies in a February 24, 2016 memorandum on how to calculate

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[4] The penalty for 46301(a)(3) is an "increase[ ] above the otherwise applicable maximum amount under this section to an amount not to exceed 3 times the amount of revenues that are used in violation of such section." As it depends on the other maximum penalties in 46301, there is no separate calculation needed for 46301(a)(3).

[5] Section 47531 explicitly states that the applicable civil penalties are "the same . . . as a person violating section 44701(a) or (b) or any of sections 44702–44716 of this title." Sections 46301(a)(1)(A) and (a)(5) provide the civil penalty amounts for those violations, and no separate calculation is needed.

[6] Section 50917 was added by the Commercial Space Launch Act, Public Law 98–575, section 19, 98 Stat. 3055, 3062 (1984), and was codified as section 70115 of title 49 before being recodified in title 51.

the initial adjustment required by the 2015 Act. The FAA must follow the direction of Congress and is using statutorily-mandated guidance provided by OMB in calculating the catch-up inflation adjustment. Applying Congress's directions and OMB's guidance, the FAA has determined that this rule imposes no additional social cost. Civil penalties are, like taxes, an economic transfer. OMB guidance A–4 states that transfers are monetary payments from one group to another and thus not a social cost. OMB further dictates that transfers should not be included in estimates of the benefits and costs due to regulation. As transfers do not add social cost, this is a minimal cost rule. OMB also directs that distributional effects of transfers should be considered. The term "distributional effect" refers to the impact of a regulatory action across the population and economy, divided up in various ways (*e.g.* income groups, race, sex, industrial sector, geography). Distributional effects may arise through transfer payments like civil penalties that stem from regulatory enforcement action. While persons paying civil penalties may experience distributional effects, these discrete effects are far outweighed by the positive effects of civil penalties. Compliance with FAA statutes and regulations is essential to safety. Civil penalties are a punishment for those who violate FAA statutes and regulations. They also deter future violations. As a result, they support the FAA's mission of aviation, hazmat, and commercial space safety, which benefits the public at large. Thus, the cost impact of this rulemaking is minimal, and a full regulatory evaluation is not required in accordance with DOT Order 2100.5.

The FAA has determined that this final rule is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866 because it does not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities for the following reasons:

(i) Based on the FAA's review of civil penalties assessed in fiscal year 2015, the total amount assessed was about $18 million. Even if this total itself were increased to the catch-up adjustment cap of a 150% increase (which is not being done here), it would only result in an increase of $27 million, bringing the total amount assessed to $45 million, which is substantially less than $100 million. Thus, the amount of the statutorily mandated inflation adjustment in this rulemaking will not have an annual effect on the economy of $100 million or more; and

(ii) The process of determining whether or not a civil penalty is imposed is not affected by this change as this rulemaking only impacts the minimum and maximum possible amount of the penalty.

The FAA has further determined that this final rule is not a "significant regulatory action" because it does not (a) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency, (b) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (c) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. Finally, the FAA has determined that this final rule is not "significant" as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation." To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration." The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The FAA believes that this final rule does not have a significant economic impact on a substantial number of small entities for the following reasons. While this final rule is likely to impact a substantial number of small entities, it will impose only minimal costs. This final rule simply identifies the amount of the inflation adjustment to existing civil monetary penalty maximums and minimums for violations of the statutory and regulatory provisions the FAA enforces. The penalty amounts are those specified by statute or called for under the inflation adjustment statutes, and the information in this rule is required by the Debt Collection Improvement Act of 1996.[7] As civil penalties are economic transfers, by OMB direction these are not included in the calculation of social costs.

In addition, FAA has determined the RFA does not apply to this rulemaking. The 2015 Act requires FAA to publish an interim final rule and there is good cause for issuing this rule without notice and comment under 5 U.S.C. 553(b)(B). The Small Business Administration's *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (2003), provides that:

> If, under the APA or any rule of general applicability governing federal grants to state and local governments, the agency is required to publish a general notice of proposed rulemaking (NPRM), the RFA must be considered [citing 5 U.S.C. 604(a)]. . . . If an NPRM is not required, the RFA does not apply.

Because there is good cause for issuing this final rule without notice and comment (*i.e.,* without an NPRM), the RFA does not apply. Therefore, as provided in section 605(b), the head of the FAA certifies that this rule will not result in a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

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[7] The 2015 Act, Public Law 114–74, codified at 28 U.S.C. 2461 note, specifies the method of calculating the inflation adjustment, and OMB Memorandum M–16–06 provides the guidance required by the 2015 Act for agencies in calculating the inflation adjustment.

The FAA has assessed the potential effect of this final rule and determined that it would impose identical inflation adjusted civil penalties on domestic and international entities that violate aviation safety, hazmat, and commercial space provisions in titles 49 and 51 of the U.S. Code and regulations issued under those provisions, and thus would have a neutral trade impact. Furthermore, the inflation adjustment is a legitimate domestic objective preserving the existing deterrent impact of aviation, hazmat, and commercial space safety statutes and regulations. Therefore, we have determined that this rule will result in a neutral impact on international trade.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there are no current or new requirements for information collection associated with this rule.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.6.f, which covers regulations not expected to cause any potentially significant environmental impacts. The FAA has also determined that there are no extraordinary circumstances requiring an environmental assessment or environmental impact statement.

Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a "significant energy action" under the executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Availability of Rulemaking Documents

You can get an electronic copy of rulemaking documents using the Internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies;* or

3. Accessing the Government Printing Office's Web page at *http://www.gpo.gov/fdsys.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the amendment number or docket number of this rulemaking.

List of Subjects

14 CFR Part 13

Administrative practice and procedure, Air transportation, Hazardous materials transportation, Investigations, Law enforcement, Penalties.

14 CFR Part 406

Administrative procedure and review, Commercial space transportation, Enforcement, Investigations, Penalties, Rules of adjudication.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapters I and III of title 14, Code of Federal Regulations as follows:

CHAPTER I—FEDERAL AVIATION ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

PART 13—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

■ 1. The authority citation for part 13 continues to read as follows:

Authority: 18 U.S.C. 6002; 28 U.S.C. 2461 (note); 49 U.S.C. 106(g), 5121–5128, 40113–40114, 44103–44106, 44701–44703, 44709–44710, 44713, 46101–46111, 46301, 46302 (for a violation of 49 U.S.C. 46504), 46304–46316, 46318, 46501–46502, 46504–46507, 47106, 47107, 47111, 47122, 47306, 47531–47532; 49 CFR 1.47.

■ 2. Amend § 13.301 by revising paragraph (a) and adding paragraph (c) to read as follows:

§ 13.301 Scope and purpose.

(a) This subpart sets out the current adjusted maximum civil monetary penalties or range of minimum and maximum civil monetary penalties for each statutory civil penalty subject to the FAA's jurisdiction under title 49 of the U.S. Code. These penalties have been adjusted for inflation in conformity with the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 (note), as amended by the Debt Collection Improvement Act of 1996, Public Law 104–134, April 26, 1996, and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114–74, November 2, 2015, in order to maintain the deterrent effect of civil monetary penalties and to promote compliance with the law.

* * * * *

(c) Minimum and maximum civil monetary penalties within the jurisdiction of the FAA are as follows:

Table of Minimum and Maximum Civil Monetary Penalty Amounts for Certain Violations Occurring on or After August 1, 2016

United States Code citation	Civil monetary penalty description	Minimum penalty amount	New or adjusted minimum penalty amount	Maximum penalty amount when last set or adjusted by Congress	New or adjusted maximum penalty amount
49 U.S.C. 5123(a), subparagraph (1).	Violation of hazardous materials transportation law.	Deleted 7/6/2012.	N/A	$75,000 per violation, adjusted 7/6/2012.	$77,114.
49 U.S.C. 5123(a), subparagraph (2).	Violation of hazardous materials transportation law resulting in death, serious illness, severe injury, or substantial property destruction.	Deleted 7/6/2012.	N/A	$175,000 per violation, adjusted 7/6/2012.	$179,933.
49 U.S.C. 5123(a), subparagraph (3).	Violation of hazardous materials transportation law relating to training.	$450 per violation, set 8/10/2005.	$537	$75,000 per violation, adjusted 7/6/2012.	$77,114.
49 U.S.C. 46301(a)(1).	Violation by a person other than an individual or small business concern under 49 U.S.C. 46301(a)(1)(A) or (B).	N/A	N/A	$25,000 per violation, set 12/12/2003.	$32,140.
49 U.S.C. 46301(a)(1).	Violation by an airman serving as an airman under 49 U.S.C. 46301(a)(1)(A) or (B) (but not covered by 46301(a)(5)(A) or (B).	N/A	N/A	$1,100 per violation, adjusted 12/12/2003.	$1,414.
49 U.S.C. 46301(a)(1).	Violation by an individual or small business concern under 49 U.S.C. 46301(a)(1)(A) or (B) (but not covered in 49 U.S.C. 46301(a)(5)).	N/A	N/A	$1,100 per violation, adjusted 12/12/2003.	$1,414.
49 U.S.C. 46301(a)(3).	Violation of 49 U.S.C. 47107(b) (or any assurance made under such section) or 49 U.S.C. 47133.	N/A	N/A	Increase above otherwise applicable maximum amount not to exceed 3 times the amount of revenues that are used in violation of such section.	No change.
49 U.S.C. 46301(a)(5)(A).	Violation by an individual or small business concern (except an airman serving as an airman) under 49 U.S.C. 46301(a)(5)(A)(i) or (ii).	N/A	N/A	$10,000 per violation, set 12/12/2003.	$12,856.
49 U.S.C. 46301(a)(5)(B)(i).	Violation by an individual or small business concern related to the transportation of hazardous materials.	N/A	N/A	$10,000 per violation, set 12/12/2003.	$12,856.
49 U.S.C. 46301(a)(5)(B)(ii).	Violation by an individual or small business concern related to the registration or recordation under 49 U.S.C. chapter 441, of an aircraft not used to provide air transportation.	N/A	N/A	$10,000 per violation, set 12/12/2003.	$12,856.
49 U.S.C. 46301(a)(5)(B)(iii).	Violation by an individual or small business concern of 49 U.S.C. 44718(d), relating to limitation on construction or establishment of landfills.	N/A	N/A	$10,000 per violation, set 12/12/2003.	$12,856.
49 U.S.C. 46301(a)(5)(B)(iv).	Violation by an individual or small business concern of 49 U.S.C. 44725, relating to the safe disposal of life-limited aircraft parts.	N/A	N/A	$10,000 per violation, set 12/12/2003.	$12,856.
49 U.S.C. 46301(b)	Tampering with a smoke alarm device	N/A	N/A	$2,000 per violation, set 12/22/1987.	$4,126.
49 U.S.C. 46302	Knowingly providing false information about alleged violation involving the special aircraft jurisdiction of the United States.	N/A	N/A	$10,000 per violation, set 10/12/1984.	$22,587.
49 U.S.C. 46318	Interference with cabin or flight crew	N/A	N/A	$25,000, set 4/5/2000	$34,172.
49 U.S.C. 46319	Permanent closure of an airport without providing sufficient notice.	N/A	N/A	$10,000 per day, set 12/12/2003.	$12,856.
49 U.S.C. 47531	Violation of 49 U.S.C. 47528–47530, relating to the prohibition of operating certain aircraft not complying with stage 3 noise levels.	N/A	N/A	See 49 U.S.C. 46301(a)(1)(A) and (a)(5), above.	No change.

§§ 13.303 and 13.305 [Removed]

■ 3. Remove §§ 13.303 and 13.305.

CHAPTER III—COMMERCIAL SPACE TRANSPORTATION, FEDERAL AVIATION ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

PART 406—INVESTIGATIONS, ENFORCEMENT, AND ADMINISTRATIVE REVIEW

■ 4. The authority citation for part 406 continues to read as follows:

Authority: 51 U.S.C. 50901–50923.

■ 5. Revise § 406.9(a) to read as follows:

§ 406.9 Civil penalties.

(a) *Civil penalty liability.* Under 51 U.S.C. 50917(c), a person found by the FAA to have violated a requirement of the Act, a regulation issued under the Act, or any term or condition of a license or permit issued or transferred under the Act, is liable to the United States for a civil penalty of not more than $225,867 for each violation. A separate violation occurs for each day the violation continues.

* * * * *

Issued under authority provided by 28 U.S.C. 2461 and 49 U.S.C. 106(f), 44701(a), and 46301 in Washington, DC, on June 23, 2016.

Michael P. Huerta,

Administrator.

[FR Doc. 2016–15744 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. FAA–2015–5034; Special Conditions No. 23–273–SC]

Special Conditions: Kestrel Aircraft Company, Model K–350 Turboprop, Lithium Batteries

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Kestrel Aircraft Company, Model K–350 Turboprop airplane. This airplane will have a novel or unusual design feature associated with the installation of a rechargeable lithium battery. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: These special conditions are effective July 5, 2016 and are applicable on June 23, 2016.

FOR FURTHER INFORMATION CONTACT: Ruth Hirt, Federal Aviation Administration, Small Airplane Directorate, Aircraft Certification Service, Programs and Procedures Branch, ACE–114, 901 Locust, Room 301, Kansas City, MO 64106; telephone (816) 329–4108, facsimile (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Background

On November 22, 2011, Kestrel Aircraft Company applied for a type certificate for their new Model K–350. The Kestrel Aircraft Company Model K–350 is a single-engine turboprop airplane with the primary structure constructed largely of carbon and epoxy composite material. The turboprop engine will be a Honeywell Model TPE331–14GR–801KT that is integrated with a Hartzell 4 bladed, 110-inch carbon composite propeller. The standard seating configuration offers a one plus five cabin (one pilot and five passengers). Alternate interior configurations will be available from two seats (cargo configuration) up to eight seats total. The K–350 will incorporate an integrated avionics system, retractable landing gear, and a conventional tail configuration.

Specifications expected for the K–350 include the following:

- Maximum altitude: 31,000 Feet
- Maximum cruise speed: 320 Knots True Air Speed
- Maximum takeoff weight: 8,900 Pounds
- Maximum economy cruise: 1,200 Nautical Miles

The K–350 will be certified for single-pilot operations under part 91 and part 135 operating rules. The following operating conditions will be included:

- Day and Night Visual Flight Rules
- Instrument Flight Rules
- Flight Into Known Icing (Phase B certification)

Kestrel Aircraft Company plans to utilize a rechargeable lithium main battery on their new Model K–350 turboprop airplane. The current regulatory requirements for part 23 airplanes do not contain adequate requirements for the application of rechargeable lithium batteries in airborne applications. This type of battery possesses certain failure and operational characteristics with maintenance requirements that differ significantly from that of the nickel-cadmium (Ni-Cd) and lead-acid rechargeable batteries currently approved in other normal, utility, acrobatic, and commuter category airplanes. Therefore, the FAA is issuing this special condition to require that (1) all characteristics of the rechargeable lithium batteries and their installation that could affect safe operation of the K–350 are addressed, and (2) appropriate Instructions for Continued Airworthiness that include maintenance requirements are established to ensure the availability of electrical power from the batteries when needed.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Kestrel Aircraft Company must show that the K–350 meets the applicable provisions of part 23, as amended by amendments 23–1 through 23–62 thereto.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 23) do not contain adequate or appropriate safety standards for the K–350 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the K–350 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the Noise Control Act of 1972.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The K–350 will incorporate the following novel or unusual design feature:

Installation of a rechargeable lithium battery as the main or engine start aircraft battery.

Discussion

The current regulatory requirements for part 23 airplanes do not contain adequate requirements for the application of rechargeable lithium batteries in electrical system design. This type of battery possesses certain failures with operational characteristics and maintenance requirements that differ significantly from that of the Ni-Cd and lead-acid rechargeable batteries currently approved in other normal, utility, acrobatic, and commuter category airplanes. Therefore, the FAA is issuing this special condition to require that (1) all characteristics of the rechargeable lithium batteries and their installation that could affect safe operation of the K–350 are addressed, and (2) appropriate Instructions for Continuous Airworthiness which include maintenance requirements are established to ensure the availability of electrical power from the batteries when needed.

As previously mentioned, Kestrel Aircraft Company plans to utilize a rechargeable lithium main battery on their new Model K–350 turboprop airplane. At the Kestrel Preliminary Type Certification Board Meeting it was brought to the attention of the FAA that the lithium battery used in the K–350 will be qualified to RTCA standards DO–311, titled Minimum Operational Performance Standards for Rechargeable Lithium Battery Systems. Additionally, on July 18, 2013, Kestrel advised the Civil Aviation Contingency Operations (CACO) that the battery will have Technical Standard Order Authorization for TSO–C179a,[1] titled Permanently Installed Rechargeable Lithium Cells, Batteries and Battery Systems. Finally, Kestrel plans to use the same manufacturer for both the lithium battery and the battery controller.

Presently, there is limited experience with use of rechargeable lithium batteries in applications involving commercial aviation. However, other users of this technology, ranging from wireless telephone manufacturers to the electric vehicle industry, have noted safety problems with lithium batteries. These problems include overcharging, over-discharging, and flammability of cell components, described in the following:

1. Overcharging: In general, lithium batteries are significantly more susceptible to internal failures that can result in self-sustaining increases in temperature and pressure (*i.e.*, thermal runaway) than the Ni-Cd or lead-acid counterparts. This is especially true for overcharging which causes heating and destabilization of the components of the cell, leading to the formation (by plating) of highly unstable metallic lithium. The metallic lithium may ignite, resulting in a fire or explosion. Finally, the severity of thermal runaway due to overcharging increases with increasing battery capacity and physical size.

2. Over-discharging: Discharge of some types of lithium battery cells beyond a certain voltage (typically 2.4 volts) can cause corrosion of the electrodes of the cell, resulting in loss of battery capacity that cannot be reversed by recharging. This loss of capacity may not be detected by the simple voltage measurements commonly available to flight crews as a means of checking battery status, which is a problem shared with Ni-Cd batteries.

3. Flammability of Cell Components: Unlike Ni-Cd and lead-acid batteries, some types of lithium batteries use liquid electrolytes that are flammable. The electrolyte may serve as a source of fuel for an external fire, if there is a breach of the battery container.

These problems experienced by users of lithium batteries raise concern about the use of these batteries in commercial aviation. The intent of the special condition is to establish appropriate airworthiness standards for lithium battery installations in the K–350 and to ensure, as required by §§ 23.1309 and 23.601, that these battery installations are neither hazardous nor unreliable.

In showing compliance with the special conditions herein, paragraphs (a)(1) through (a)(8), and the RTCA document, Minimum Operational Performance Standards for Rechargeable Lithium Battery Systems, DO–311, may be used. The list of planned DO–311 tests should be documented in the certification or compliance plan and agreed to by the CACO. Alternate methods of compliance other than DO–311 tests must be coordinated with the directorate and CACO.

Discussion of Comments

Notice of proposed special conditions No. 23–15–01–SC[2] for the Kestrel Aircraft Company Model K–350 Turboprop airplanes was published in the **Federal Register** on November 4, 2015 (80 FR 68281). No comments were received, and the special conditions are adopted as proposed.

Applicability

These special conditions are not intended to replace § 23.1353(a)(b)(c)(d)(e) at amendment 23–62 in the certification basis of Model K–350 airplanes. These special conditions apply only to rechargeable lithium batteries and lithium battery systems and their installations. The requirements of § 23.1353 at amendment 23–62 remains in effect for batteries and battery installations on K–350 series that do not use newly technologically developed batteries.

As previously discussed, these special conditions are applicable to the K–350. Should Kestrel Aircraft Company apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the **Federal Register**; however, as the certification date for the Kestrel Aircraft Company Model K–350 Turboprop airplane is imminent, the FAA finds that good cause exists to make these special conditions effective upon issuance.

Conclusion

This action affects only certain novel or unusual design features on one model of airplane. It is not a rule of general applicability and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113 and 44701; 14 CFR 21.16 and 21.17; and 14 CFR 11.38 and 11.19.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Kestrel Aircraft Company, Model K–350 Turboprop airplanes.

1. Kestrel Aircraft Company, Model K–350 Turboprop, Lithium Batteries.

The FAA issues special conditions that adopt the following requirements that must be applied to all rechargeable lithium battery and lithium battery installations in lieu of the requirements of § 23.1353(a)(b)(c)(d)(e), amendment 23–62:

(a) Rechargeable lithium batteries and battery installations must be designed and installed as follows:

(1) Safe cell temperatures and pressures must be maintained during—

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[1] *http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgTSO.nsf/0/A3B77A692AE3FF9386257885004B079C?OpenDocument.*

[2] *https://www.regulations.gov/#!documentDetail;D=FAA-2015-5034-0001.*

i. normal operations;

ii. any probable failure conditions of charging or discharging or battery monitoring system; or

iii. any failure of the charging or battery monitoring system not shown to be extremely remote.

(2) The rechargeable lithium battery installation must be designed to preclude explosion or fire in the event of (e)(1)(ii) and (e)(1)(iii) failures.

(3) Design of the rechargeable lithium batteries must preclude the occurrence of self-sustaining, uncontrolled increases in temperature or pressure.

(4) No explosive or toxic gasses emitted by any rechargeable lithium battery in normal operation or as the result of any failure of the battery charging system, monitoring system, or battery installation that is not shown to be extremely remote, may accumulate in hazardous quantities within the airplane.

(5) Installations of rechargeable lithium batteries must meet the requirements of § 23.863(a) through (d) at amendment 23–34.

(6) No corrosive fluids or gases that may escape from any rechargeable lithium battery may damage surrounding structure or any adjacent systems, equipment, electrical wiring, or the airplane in such a way as to cause a major or more severe failure condition, in accordance with § 23.1309(c) at amendment 23–62 and applicable regulatory guidance.

(7) Each rechargeable lithium battery installation must have provisions to prevent any hazardous effect on structure or essential systems that may be caused by the maximum amount of heat the battery can generate during a short circuit of the battery or of its individual cells.

(8) Rechargeable lithium battery installations must have—

i. a system to automatically control the charging rate of the battery to prevent battery overheating and overcharging;

ii. a battery temperature sensing and over-temperature warning system with a means of automatically disconnecting the battery from its charging source in the event of an over-temperature condition; and

iii. a battery failure sensing and warning system with a means of automatically disconnecting the battery from its charging source in the event of battery failure.

(b) Any rechargeable lithium battery installation functionally required for safe operation of the airplane must incorporate a monitoring and warning feature that will provide an indication to the appropriate flight crewmembers whenever the State of Charge (SOC) of the batteries has fallen below levels considered acceptable for dispatch of the airplane.

(c) The Instructions for Continued Airworthiness required by § 23.1529 at amendment 23–26 must contain maintenance requirements to assure that the battery has been sufficiently charged at appropriate intervals specified by the battery manufacturer and the equipment manufacturer that contain the rechargeable lithium battery or rechargeable lithium battery system. This is required to ensure that lithium rechargeable batteries and lithium rechargeable battery systems will not degrade below specified ampere-hour levels sufficient to power the aircraft system. The Instructions for Continued Airworthiness must also contain procedures for the maintenance of replacement batteries in spares storage to prevent the installation of batteries that have degraded charge retention ability or other damage due to prolonged storage at a low state of charge. Replacement batteries must be of the same manufacturer and part number as approved by the FAA.

Issued in Kansas City, Missouri, on June 23, 2016.

William Schinstock,

Acting Manager, Small Airplane Directorate Aircraft Certification Service.

[FR Doc. 2016–15765 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2015–8298; Special Conditions No. 25–611–SC]

Special Conditions: JAMCO America, Inc., Boeing Model 777–300ER, Dynamic Test Requirements for Single-Occupant Oblique (Side-Facing) Seats With Inflatable Restraints

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special condition; request for comments; corrections.

SUMMARY: This document corrects omissions in docket no. FAA–2015–8298, special conditions no. 25–611–SC, which was published in the **Federal Register** on March 16, 2016 (81 FR 13969). The special conditions in the published document are incomplete. This correction replaces the entire special conditions section from that which appeared in the original **Federal Register** publication.

DATES: This action is effective on JAMCO America, Inc., on July 5, 2016. We must receive your comments August 19, 2016.

FOR FURTHER INFORMATION CONTACT: John Shelden, FAA, Airframe and Cabin Safety Branch, ANM–115,Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2785; facsimile (425) 227–1320.

SUPPLEMENTARY INFORMATION: On March 16, 2016, the **Federal Register** published a document designated as "Docket No. FAA–2015–8298; Special Conditions No. 25–611–SC," (81 FR 13969). That document issued special conditions pertaining to dynamic test requirements for single-occupant oblique (side-facing) seats with inflatable restraints on Boeing Model 777–300ER airplanes. As published, the special conditions are incomplete. The applicant was aware of the complete set of conditions at the time of the original, incomplete publication.

Correction

The following special conditions replace the entire special conditions section of the final special conditions document [FR Doc. 2016–05995 Filed 3–15–16; 8:45 a.m.], published on March 16, 2016 (81 FR 13969). The introductory language was previously published and is not changed.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 777–300ER airplanes modified by JAMCO.

Oblique (Side-Facing) Seats Special Conditions

In addition to the requirements of § 25.562:

1. Head Injury Criteria (HIC)

Compliance with § 25.562(c)(5) is required, except that, if the anthropomorphic test device (ATD) has no apparent contact with the seat and related structure but has contact with an airbag, a HIC unlimited score in excess of 1000 is acceptable, provided the HIC15 score (calculated in accordance with 49 CFR 571.208) for that contact is less than 700.

2. Body-to-Wall/Furnishing Contact

If a seat is installed aft of structure (*e.g.* interior wall or furnishings) that does not provide a homogenous contact surface for the expected range of occupants and yaw angles, then additional analysis and tests may be required to demonstrate that the injury criteria are met for the area that an occupant could contact. For example, if different yaw angles could result in different airbag device performance, then additional analysis or separate tests may be necessary to evaluate performance.

3. Neck Injury Criteria

a. The seating system must protect the occupant from experiencing serious neck injury. The assessment of neck injury must be conducted with the airbag device activated, unless there is reason to also consider that the neck-injury potential would be higher for impacts below the airbag-device deployment threshold.

b. The N_{ij}, calculated in accordance with 49 CFR 571.208, must be below 1.0, where $N_{ij} = F_z/F_{zc} + M_y/M_{yc}$, and N_{ij} critical values are:

i. F_{zc} = 1530 lb for tension
ii. F_{zc} = 1385 lb for compression
iii. M_{yc} = 229 lb-ft in flexion
iv. M_{yc} = 100 lb-ft in extension

c. In addition, peak upper neck F_z must be below 937 lb in tension and 899 lb in compression.

d. Rotation of the head about its vertical axis relative to the torso is limited to 105 degrees in either direction from forward-facing.

e. The neck must not impact any surface that would produce concentrated loading on the neck.

4. Spine and Torso Injury Criteria

a. The lumbar spine tension (F_z) cannot exceed 1200 lb.

b. Significant concentrated loading on the occupant's spine, in the area between the pelvis and shoulders during impact, including rebound, is not acceptable. During this type of contact, the interval for any rearward (X-axis direction) acceleration exceeding 20g must be less than 3 milliseconds as measured by the thoracic instrumentation specified in 49 CFR part 572, subpart E, filtered in accordance with SAE recommended practice J211/1, "Instrumentation for Impact Test—Part 1—Electronic Instrumentation."

c. The occupant must not interact with the armrest or other seat components in any manner significantly different than would be expected for a forward-facing seat installation.

5. Pelvis Criteria

Any part of the load-bearing portion of the bottom of the ATD pelvis must not translate beyond the edges of the seat bottom seat-cushion supporting structure.

6. Femur Criteria

Axial rotation of the upper leg (about the Z-axis of the femur, per SAE J211/1) must be limited to 35 degrees in the strike direction from the normal seating position. Evaluation during rebound need not be considered.

7. ATD and Test Conditions

Longitudinal tests conducted to measure the injury criteria above must be performed with the FAA Hybrid III ATD, as described in SAE 1999–01–1609, "A Lumbar Spine Modification to the Hybrid III ATD For Aircraft Seat Tests." The tests must be conducted with an undeformed floor, at the most-critical yaw cases for injury, and with all lateral structural supports (*e.g.* armrests or walls) installed.

Inflatable Lapbelt Special Conditions

The inflatable lapbelts must meet special conditions no. 25–187A–SC, "Boeing Model 777 Series Airplanes; Seats with Inflatable Lapbelts."

1. Because this type of protection system may or may not activate during various crash conditions, the applicant must demonstrate that the injury criteria listed in these special conditions are not exceeded in an event which is slightly below the activation level of the airbag system.

2. Additionally, as indicated in special conditions no. 25–187A–SC, inflatable lapbelts must be shown to not affect emergency-egress capabilities in the main aisle, cross-aisle, and passageway.

Issued in Renton, Washington, on June 17, 2016.

Michael Kaszycki,

Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–15784 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–8134; Directorate Identifier 2014–NM–256–AD; Amendment 39–18572; AD 2016–13–08]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A300 series airplanes; and Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). This AD was prompted by a report of cracking of the lower tension bolt area at the rib one junction (both sides) of the lower wing. This AD requires repetitive inspections for cracking of the fasteners and of the fitting around the fastener holes at the frame (FR) 40 lower wing location, and corrective actions if necessary. We are issuing this AD to detect and correct crack initiation of the fittings of the FR40 lower wing locations, which could result in reduced structural integrity of the airplane.

DATES: This AD becomes effective August 9, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 9, 2016.

ADDRESSES: For Airbus service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com*; Internet *http://www.airbus.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–8134.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–8134; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Model A300 series airplanes; and Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). The NPRM published in the **Federal Register** on December 31, 2015 (80 FR 81786) ("the NPRM").

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0272, dated December 12, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for all Airbus Model A300 series airplanes; and Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes). The MCAI states:

> Following the A300–600 Extended Service Goal (ESG2) exercise, specific inspections for cracks were performed in fittings of frame (FR) 40, in areas not covered by any existing task.
>
> Findings were identified on an A300–600 aeroplane withdrawn from service in the lower tension bolt area at rib one junction (both sides).
>
> This condition, if not detected and corrected, could lead to crack initiation, affecting the structural integrity of the aeroplane.
>
> To address this potential unsafe condition, an inspection programme was developed for the fitting around the fastener holes located at FR40 lower wing junction, left-hand (LH) and right-hand (RH) sides.
>
> For the reasons described above, this [EASA] AD requires repetitive High Frequency Eddy Current (HFEC) inspections and rototest inspections of the fitting around the fastener holes located at FR40 lower wing junction and, depending on findings, accomplishment of a repair.

The corrective actions include a repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA Design Organization Approval (DOA).

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–8134.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Clarify Corrective Actions

FedEx asked that the corrective actions identified in paragraph (i) of the proposed AD be clarified. FedEx stated that paragraph (h)(1) of the proposed AD specifies "If one or more of the hole diameters is outside the tolerance of the nominal diameter, and outside the tolerance of the first and second oversize: Do the applicable corrective actions required by paragraph (i) of this AD." FedEx added that paragraph (i) of the proposed AD specifies "If, during any inspection required by this AD, any crack is found, or one or more of the hole diameters are outside the tolerance of the nominal diameter: Repair before further flight using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA)." FedEx noted that paragraph (i) should specify "one or more of the hole diameters are outside the tolerance of the nominal diameter and outside the tolerance of the first and second oversize" to match the language in paragraph (h)(1) of the proposed.

We agree. We have confirmed that the language in paragraph (i) of this AD should match the language in paragraph (h)(1) of this AD. We have changed paragraph (i) of this AD accordingly.

Request To Revise Compliance Time

United Parcel Service (UPS) asked that we revise the compliance time for the rototest inspections specified by paragraph (h) of the proposed AD to a threshold based on total service time, rather than calendar time alone. UPS stated that, based on reported findings to date, the crack growth rate is so slow it will not affect the immediate airworthiness of the airplane. UPS suggested that we add a threshold of 11,900 total flight cycles.

We do not agree with the commenter's request. The commenter provided no data to substantiate the proposed compliance time based on flight cycles. In developing an appropriate compliance time for this AD, we considered not only the urgency associated with the subject unsafe condition, but also the manufacturer's recommendations, EASA's recommendations, and the practical aspect of accomplishing the required inspections within a period of time that corresponds to the normal scheduled maintenance for most affected operators. After considering all the available information, we have determined that the compliance time, as proposed, represents an appropriate interval of time in which the required actions can be performed in a timely manner within the affected fleet, while still maintaining an adequate level of safety. However, affected operators may request an alternative method of compliance (AMOC) to request a change to the compliance time under the provisions of paragraph (j) of this AD by submitting data and analysis substantiating that the change would provide an acceptable level of safety. We have not changed this AD regarding this issue.

Request To Remove High Frequency Eddy Current (HFEC) Inspections

UPS asked that the HFEC inspections specified by paragraph (g) of the proposed AD be removed. UPS stated that the HFEC inspection requirement does not enhance airplane safety because only substantial damage can be detected by this method, due to a restricted inspection area. UPS also stated that the smallest crack detectable by an HFEC inspection method is calculated to be 7.5 mm in length, not taking into account the inspection surface radius and the limited access to the inspection area. UPS added that fastener location and potential obstacles affect consistent probe movement, which increases the chance for inconsistent inspection readings.

We do not agree with the commenter's request. The HFEC inspection required by paragraph (g) of this AD is a necessary interim measure intended to find cracking before the required compliance time for the rototest inspection in paragraph (h) of this AD. As the commenter acknowledged, a 7.5-mm crack may be detected during an HFEC inspection within 1,000 flight hours. That same 7.5-mm crack, undetected for 3 years until the rototest inspection is done, could grow and result in reduced structural integrity of the airplane; therefore, the repetitive HFEC inspections must be retained in this AD. If no cracking is found, the HFEC inspection can be repeated, or terminated when the rototest inspection is accomplished. However, affected operators may request approval of an AMOC to do the rototest inspections only, under the provisions of paragraph (j) of this AD by submitting data and analysis, and a compliance schedule, substantiating that the change would provide an acceptable level of safety. We have not changed this AD regarding this issue.

Request To Correct Typographical Errors in Service Information

FedEx asked that the typographical errors for the structural repair manual (SRM) references in Airbus Service Bulletin A300–57–6115, dated April 4, 2014, be corrected so FedEx can use them to comply with the NPRM requirements. FedEx stated that Airbus was informed of and acknowledged these typographical errors, but currently no changes have been made to the service information. FedEx noted that the service information listed SRM 51–40–13 for the application of special coatings, but the correct reference is SRM 51–23–20. FedEx also noted that the service information listed SRM 51–40–12 for the application of paint coatings, but the correct reference is SRM 51–23–10.

We agree with the commenter's concerns. We have changed paragraph (g) of this AD to clarify the correct SRM references to be used.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information.

- Airbus Service Bulletin A300–57–0257, excluding Appendix 01 and including Appendix 02, dated April 4, 2014.
- Airbus Service Bulletin A300–57–6115, dated April 4, 2014.

The service information describes procedures for repetitive inspections for cracking of the fasteners and of the fitting around the fastener holes at the FR40 lower wing location. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

We estimate that this AD affects 166 airplanes of U.S. registry.

We also estimate that it takes about 12 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be $169,320, or $1,020 per product.

We have received no definitive data that would enable us to provide a cost estimate for the on-condition actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–13–08 Airbus: Amendment 39–18572. Docket No. FAA–2015–8134; Directorate Identifier 2014–NM–256–AD.

(a) Effective Date

This AD becomes effective August 9, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Airbus Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes.

(2) Airbus Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, F4–605R, F4–622R, and C4–605R Variant F airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by a report of cracking of the lower tension bolt area at rib one junction (both sides) of the lower wing. We are issuing this AD to detect and correct crack initiation of the fittings of the frame (FR) 40 lower wing locations, which could result in reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive High Frequency Eddy Current (HFEC) Inspections

Within 1,000 flight hours after the effective date of this AD: Do an HFEC inspection for cracking of fasteners 1 through 3 at the left-hand and right-hand sides of the FR40 lower junction, and of the fitting around the fastener holes, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–0257, excluding Appendix 01 and including Appendix 02, dated April 4, 2014 (for Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes); or Airbus Service Bulletin A300–57–6115, dated April 4, 2014 (for Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, F4–605R, F4–622R, and C4–605R Variant F airplanes). If no cracking is found, repeat the HFEC inspection at intervals not to exceed 1,000 flight hours until a rototest inspection required by paragraph (h)(2) of this AD has been done. Where Airbus Service Bulletin

A300–57–6115, dated April 4, 2014, refers to Structural Repair Manual (SRM) 51–40–13 for applying special protection, the correct reference is SRM 51–23–20; and to SRM 51–40–12 for applying paint coatings, the correct reference is SRM 51–23–10.

(h) Repetitive Rototest Inspections

Within 36 months after the effective date of this AD: Remove the fasteners and measure the diameter of the fastener holes; and, before further flight, do the applicable actions required by paragraph (h)(1) or (h)(2) of this AD, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–0257, excluding Appendix 01 and including Appendix 02, dated April 4, 2014 (for Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes); or Airbus Service Bulletin A300–57–6115, dated April 4, 2014 (for Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, F4–605R, F4–622R, and C4–605R Variant F airplanes).

(1) If one or more of the hole diameters is outside the tolerance of the nominal diameter, and outside the tolerance of the first and second oversize: Do the applicable corrective actions required by paragraph (i) of this AD.

(2) If all of the hole diameters are within the tolerance of the nominal diameter or the first or second oversize: Do detailed and rototest inspections for cracking of the fastener holes at the left-hand and right-hand sides of the FR40 lower junction, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–57–0257, excluding Appendix 01 and including Appendix 02, dated April 4, 2014 (for Model A300 B2–1A, B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes); or Airbus Service Bulletin A300–57–6115, dated April 4, 2014 (for Model A300 B4–601, B4–603, B4–620, B4–622, B4–605R, B4–622R, F4–605R, F4–622R, and C4–605R Variant F airplanes). If no cracking is found, before further flight, install new fasteners of the same diameter in special clearance fit for fasteners 1 through 3 of the FR40 lower junction, in accordance with the Accomplishment Instructions of Airbus Service Bulletins A300–57–0257, excluding Appendix 01 and including Appendix 02, dated April 4, 2014; or Airbus Service Bulletin A300–57–6115, dated April 4, 2014. Repeat the rototest inspection thereafter at intervals not to exceed 7,000 flight cycles. Accomplishment of a rototest inspection required by this paragraph terminates the repetitive HFEC inspections required by paragraph (g) of this AD.

(i) Corrective Actions

If, during any inspection required by this AD, any crack is found, or one or more of the hole diameters is outside the tolerance of the nominal diameter, and outside the tolerance of the first and second oversize: Repair before further flight in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) Required for Compliance (RC): Except as required by paragraph (i) of this AD: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0272, dated December 12, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–8134.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Service Bulletin A300–57–0257, excluding Appendix 01 and including Appendix 02, dated April 4, 2014.

(ii) Airbus Service Bulletin A300–57–6115, dated April 4, 2014.

(3) For Airbus service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on June 21, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–15356 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–8131; Directorate Identifier 2015–NM–073–AD; Amendment 39–18575; AD 2016–13–11]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2008–05–06 for certain The Boeing Company Model 737–100, –200, –300, –400, and –500 series airplanes. AD 2008–05–06 required repetitive inspections for fatigue cracking in the longitudinal floor beam web, upper chord, and lower chord located at certain body stations, and repair if necessary. This new AD requires, for certain airplanes, an inspection to determine if tapered fillers are installed, and related investigative and corrective actions if necessary. This AD was prompted by reports of cracks in the center wing box longitudinal floor beams, upper chord, and lower chord. We are issuing this AD to detect and correct fatigue cracking of the upper and lower chords and web of the longitudinal floor beams, which could result in rapid loss of cabin pressure.

DATES: This AD is effective August 9, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 9, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of April 8, 2008 (73 FR 11538, March 4, 2008).

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–8131.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov.* by searching for and locating Docket No. FAA–2015–8131; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Galib Abumeri, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5324; fax: 562–627–5210; email: *galib.abumeri@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2008–05–06, Amendment 39–15400 (73 FR 11538, March 4, 2008) (“AD 2008–05–06”). AD 2008–05–06 applied to certain The Boeing Company Model 737–100, –200, –300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on January 12, 2016 (81 FR 1345) (“the NPRM”). The NPRM was prompted by reports of cracks in the center wing box longitudinal floor beams, upper chord, and lower chord. The NPRM proposed to continue to require repetitive inspections for fatigue cracking in the longitudinal floor beam web, upper chord, and lower chord located at certain body stations, and repair if necessary. The NPRM also proposed to require, for certain airplanes, an inspection to determine if tapered fillers are installed, and related investigative and corrective actions if necessary. We are issuing this AD to detect and correct fatigue cracking of the upper and lower chords and web of the longitudinal floor beams, which could result in rapid loss of cabin pressure.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM

Boeing stated that it has reviewed the NPRM and concurs with the contents.

Ms. Kathleen Whitworth stated that the NPRM is a good idea because the safety of airline passengers outweighs the extra cost of the added inspection and that she is in full support of the NPRM.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf*) does not affect accomplishment of the actions specified in the NPRM.

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) and added a new paragraph (c)(2) to this AD to state that installation of STC ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a “change in product” alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously, and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015. The service information describes procedures for various inspections for fatigue cracks in the longitudinal floor beam web, upper chord, and lower chord, located at the applicable body stations, repairs (including related investigative and corrective actions), and preventive modifications (including related investigative and corrective actions) that terminate the repetitive inspections. The service information also describes procedures for an inspection to determine if tapered fillers are installed, and related investigative and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 652 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections [retained actions from AD 2008–05–06].	Up to 25 work-hours × $85 per hour = $2,125 per inspection cycle.	$0	$2,125 per inspection cycle.	$1,385,500 per inspection cycle.
Tapered filler inspection [new action]	4 work-hours × $85 per hour = $340	$0	$340	$221,680.

We estimate the following costs to do any necessary repairs that would be required based on the results of the inspection. We have no way of determining the number of aircraft that might need these repairs:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Floor beam repair and optional preventative modification.	Up to 198 work-hours × $85 per hour = $16,830	(1)	Up to $16,830
Tapered filler repair	174 work-hours × $85 per hour = $14,790	(1)	$14,790

[1] We have received no definitive data that would enable us to provide parts cost estimates for the actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2008–05–06, Amendment 39–15400 (73 FR 11538, March 4, 2008), and adding the following new AD:

2016–13–11 The Boeing Company: Amendment 39–18575; Docket No. FAA–2015–8131; Directorate Identifier 2015–NM–073–AD.

(a) Effective Date

This AD is effective August 9, 2016.

(b) Affected ADs

This AD replaces AD 2008–05–06, Amendment 39–15400 (73 FR 11538, March 4, 2008) ("AD 2008–05–06").

(c) Applicability

(1) This AD applies to The Boeing Company Model 737–100, –200, –300, –400, and –500 series airplanes; certificated in any category; as identified in Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/ebd1cec7b301293e86257cb30045557a/$FILE/ST01219SE.pdf*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a "change in product" alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports of cracks in the center wing box longitudinal floor beams, upper chord, and lower chord. We are issuing this AD to detect and correct fatigue cracking of the upper and lower chords and web of the longitudinal floor beams, which could result in rapid loss of cabin pressure.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Inspections, With Revised Service Information and Revised Affected Airplanes

This paragraph restates the requirements of paragraph (f) of AD 2008–05–06, with revised service information and revised affected airplanes. For Groups 1 through 4 airplanes identified in Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, do the various inspections for fatigue cracks in the longitudinal floor beam web, upper chord, and lower chord, located at the applicable body stations specified in the Accomplishment Instructions of Boeing Service Bulletin 737–57–1296, dated June 13, 2007; or Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015; by doing all the actions in accordance with the Accomplishment Instructions of Boeing

Service Bulletin 737–57A1296, dated June 13, 2007; or Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015; except as provided by paragraph (h) of this AD. Do the inspections at the time specified in paragraph (g)(1) or (g)(2) of this AD, as applicable. As of the effective date of this AD, only use Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, for accomplishing the actions required by this paragraph.

Note 1 to paragraphs (g) and (h) of this AD: The airplane groups identified in Boeing Service Bulletin 737–57–1296, dated June 13, 2007, do not, in all cases, match the airplane groups identified in Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015 (Group 4 airplanes in Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, coincide with certain Group 2 airplanes in Boeing Service Bulletin 737–57–1296, dated June 13, 2007).

(1) For Groups 1 and 2 airplanes, except for line numbers 1 through 291, identified in Boeing Service Bulletin 737–57–1296, dated June 13, 2007: Do the inspections at the applicable initial compliance time listed in paragraph 1.E., "Compliance," of Boeing Service Bulletin 737–57–1296, dated June 13, 2007, except where Boeing Service Bulletin 737–57–1296, dated June 13, 2007, specifies a compliance time after the date on the service bulletin, this AD requires compliance within the specified compliance time after April 8, 2008 (the effective date of AD 2008–05–06). Repeat the inspections thereafter at the intervals specified in paragraph 1.E., "Compliance," of Boeing Service Bulletin 737–57–1296, dated June 13, 2007.

(2) For Group 3 airplanes identified in Boeing Service Bulletin 737–57–1296, dated June 13, 2007: Do the inspections at the applicable initial compliance time listed in paragraph 1.E., "Compliance," of Boeing Service Bulletin 737–57–1296, dated June 13, 2007, except where Boeing Service Bulletin 737–57–1296, dated June 13, 2007, specifies a compliance time after the date on the service bulletin, this AD requires compliance within the specified compliance time after April 8, 2008 (the effective date of AD 2008–05–06). Repeat the inspections thereafter at the intervals specified in paragraph 1.E., "Compliance," of Boeing Service Bulletin 737–57–1296, dated June 13, 2007.

(h) Retained Repair Instructions, With Revised Service Information That Contains New Repair Actions

This paragraph restates the requirements of paragraph (g) of AD 2008–05–06, with revised service information that contains new repair actions. If any crack is found during any inspection required by paragraph (g) of this AD, do the applicable actions specified in paragraph (h)(1) or (h)(2) of this AD.

(1) For inspections done using Boeing Service Bulletin 737–57–1296, dated June 13, 2007: If any crack is found during any inspection required by paragraph (g) of this AD, and Boeing Service Bulletin 737–57–1296, dated June 13, 2007, specifies contacting Boeing for repair instructions, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (n) of this AD.

(2) For inspections done using Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015: If any crack is found during any inspection required by paragraph (g) of this AD, before further flight, repair, including doing all applicable related investigative actions and corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015; except where Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, specifies contacting Boeing for repair instructions, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (n) of this AD. Accomplishing a repair specified in Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, terminates the repetitive inspections required by paragraph (g) of this AD for the repaired area only.

(i) New Requirement of This AD: Inspection for Tapered Fillers for Certain Airplanes, Related Investigative Actions, and Corrective Actions

For Groups 1 through 4, Configuration 1 airplanes identified in Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015: Except as provided by paragraph (k) of this AD, at the applicable time specified in table 5 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, do an inspection to determine if tapered fillers are installed; and do all applicable related investigative and corrective actions; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015; except where Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, specifies contacting Boeing for repair instructions, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (n) of this AD. Do all applicable related investigative and corrective actions before further flight. A review of the maintenance records is acceptable in lieu of this inspection if the installation of tapered fillers can be conclusively determined from that review.

(j) New Requirement of This AD: Inspections and Corrective Actions for Group 5 Airplanes

For Group 5 airplanes identified in Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015: Except as provided by paragraph (k) of this AD, at the applicable time specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015; accomplish inspections and applicable corrective actions using a method approved in accordance with the procedures specified in paragraph (n) of this AD.

(k) Exception to Service Information

Where paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, specifies a compliance time "after the Revision 2 date of this service bulletin," this AD requires compliance within the specified compliance time "after the effective date of this AD."

(l) Optional Terminating Action

Accomplishing the applicable preventative modification specified in paragraph 3.B.4., "Preventive Modification" of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, terminates the applicable repetitive inspection required by paragraph (g) of this AD. The preventative modification, including related investigative and corrective actions, must be done in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015; except where Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015, specifies contacting Boeing for repair instructions, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (n) of this AD.

(m) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g) and (h)(2) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 737–57–1296, Revision 1, dated September 26, 2012. This document is not incorporated by reference in this AD.

(n) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (o)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(4) AMOCs approved as specified in the fourth paragraph (related to AD 2008–05–06) of Section 1.F., Approval, of Boeing Service Bulletin 737–57–1296, Revision 1, dated September 26, 2012, for repairs and modifications are not approved for any provision of this AD. All other AMOCs approved for AD 2008–05–06 are approved as AMOCs for the corresponding provisions of this AD.

(o) Related Information

(1) For more information about this AD, contact Galib Abumeri, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5324; fax: 562–627–5210; email: *galib.abumeri@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(5) and (p)(6) of this AD.

(p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on August 9, 2016.

(i) Boeing Alert Service Bulletin 737–57A1296, Revision 2, dated April 1, 2015.

(ii) Reserved.

(4) The following service information was approved for IBR on April 8, 2008 (73 FR 11538, March 4, 2008).

(i) Boeing Service Bulletin 737–57–1296, dated June 13, 2007.

(ii) Reserved.

(5) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on June 21, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–15355 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8032; Directorate Identifier 2016–SW–037–AD; Amendment 39–18578; AD 2016–12–51]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: We are publishing a new airworthiness directive (AD) for Airbus Helicopters Model AS332L2 and Model EC225LP helicopters, which was sent previously to all known U.S. owners and operators of these helicopters. This AD immediately prohibits flight of all Model AS332L2 and EC225LP helicopters. This AD is prompted by an accident involving an EC225LP helicopter in which the main rotor hub (MRH) detached from the main gearbox (MGB). These actions are intended to prevent failure of the main rotor system and subsequent loss of control of the helicopter.

DATES: This AD becomes effective July 20, 2016 to all persons except those persons to whom it was made immediately effective by Emergency AD 2016–12–51, issued on June 3, 2016, which contains the requirements of this AD.

We must receive comments on this AD by September 6, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8032; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Gary Roach, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110, email *gary.b.roach@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

On June 3, 2016, we issued Emergency AD 2016–12–51 to correct an unsafe condition for Model AS332L2 and EC225LP helicopters. Emergency AD 2016–12–51 immediately prohibits further flight of Model AS332L2 and EC225LP helicopters. The emergency AD was sent previously to all known U.S. owners and operators of these helicopters.

Emergency AD 2016–12–51 was prompted by Emergency AD No. 2016–0104–E, dated June 2, 2016, issued by EASA, which is the Technical Agent for the Member States of the European

Union, to correct an unsafe condition for Airbus Helicopters Model EC 225 LP helicopters. Following a fatal accident in Norway in which the MRH detached from the MGB in-flight, EASA issued Emergency AD No. 2016–0089–E, dated May 3, 2016, to require a one-time inspection of the MGB and to report findings to EASA and Airbus Helicopters. Review of the findings from the inspections prompted Airbus Helicopters to provide further inspections and replacement instructions for correctly installing the MGB suspension bars and attachment fittings. EASA subsequently issued Emergency AD No. 2016–0103–E, dated June 1, 2016, which superseded Emergency AD No. 2016–0089–E, and required inspecting the MGB suspension bar fittings and related base plate assemblies and replacing the attachment hardware. Soon after Emergency AD No. 2016–0103–E was issued, a preliminary report from the Accident Investigation Board Norway indicated metallurgical findings of fatigue and surface degradation in the outer race of a second stage planet gear of the MGB epi-cyclic module. EASA advises that it could not be determined if the fatigue and surface degradation is a contributing factor or if it resulted from another initiating factor. Therefore, pending further investigation to determine the root cause of the reported damage and pending development of mitigating measures by Airbus Helicopters, EASA decided to temporarily ground the fleet as a precautionary measure and issued Emergency AD No. 2016–0104–E on June 2, 2016. EASA included Model AS 332 L2 helicopters to the applicability due to similarities in design that make it subject to the same unsafe condition.

FAA's Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

AD Requirements

This AD immediately prohibits flight of all Airbus Helicopters Model AS332L2 and EC225LP helicopters.

Interim Action

We consider this AD to be an interim action. Once the design approval holder develops a modification that addresses the unsafe condition identified in this AD, we might consider additional rulemaking.

Costs of Compliance

We estimate that this AD affects five helicopters of U.S. Registry. There are no costs of compliance with this AD because there are no required maintenance actions.

FAA's Justification and Determination of the Effective Date

Providing an opportunity for public comments prior to adopting these AD requirements would delay implementing the safety actions needed to address this known unsafe condition. Therefore, we find the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because the previously described unsafe condition can adversely affect the airworthiness of the helicopter and the prohibition of all flights must begin immediately.

Since it was found that immediate action was required, notice and opportunity for prior public comment before issuing this AD were impracticable and contrary to the public interest and good cause existed for making Emergency AD 2016–12–51 effective immediately on June 3, 2016, to all known U.S. operators of the specified Airbus helicopters. These conditions still exist and the Emergency AD is hereby published in the **Federal Register** as an amendment to § 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–12–51 Airbus Helicopters: Amendment 39–18578; Docket No. FAA–2016–8032; Directorate Identifier 2016–SW–037–AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS332L2 and Model EC225LP helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of the main rotor system, which will result in loss of control of the helicopter.

(c) Effective Date

This AD becomes effective July 20, 2016 to all persons except those persons to whom it was made immediately effective by Emergency AD 2016–12–51 issued on June 3, 2016, which contains the requirements of this AD.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Action

Further flight is prohibited.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Gary Roach, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) Emergency AD 2016–0104–E, dated June 2, 2016. You may view the EASA AD on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2016–8032.

(h) Subject

Joint Aircraft Service Component (JASC) Code: Main Rotor Gearbox: 6320.

Issued in Fort Worth, Texas, on June 23, 2016.

James A. Grigg,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–15624 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–7422; Directorate Identifier 2016–NM–079–AD; Amendment 39–18579; AD 2016–13–14]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model DHC–8–400 series airplanes. This AD requires an inspection to determine if certain left and right main landing gear (MLG) retract actuator rod ends are installed and repetitive liquid penetrant inspections (LPIs) of affected left and right MLG retract actuator rod ends, and corrective actions if necessary. This AD also provides optional terminating action for the inspections. This AD was prompted by a report of cracked MLG retract actuator rod ends. We are issuing this AD to detect and correct fatigue cracking of the left and right MLG retract actuator rod ends, which could lead to left or right MLG collapse.

DATES: This AD becomes effective July 20, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 20, 2016.

We must receive comments on this AD by August 19, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone: 416–375–4000; fax: 416–375–4539; email: *thd.qseries@aero.bombardier.com;* Internet: *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7422.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7422; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE–171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7329; fax: 516–794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2016–16, dated May 20, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model DHC–8–400 series airplanes. The MCAI states:

> There has been a single reported case of a cracked MLG retract actuator rod end in service. A supplier disclosure letter and subsequent Bombardier analysis indicate that the MLG retract actuator rod end P/N [part number] P3A2750 and P3A2750–1 may develop fatigue cracking. This condition, if not corrected, could lead to left hand (LH) or right hand (RH) MLG collapse.
>
> This [Canadian] AD mandates the inspection [to determine if certain left and right main landing gear MLG retract actuator rod ends are installed, repetitive LPIs of affected left and right MLG retract actuator rod ends, and corrective actions if necessary], and replacement of the LH and RH MLG retract actuator rod ends P/N P3A2750 and P3A2750–1 [which is terminating action for the repetitive LPIs].

Corrective actions includes replacing cracked MLG retract actuator rod ends. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7422.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc. has issued Service Bulletin 84–32–142, dated May 4, 2016. The service information describes procedures for an inspection to determine if certain left and right MLG retract actuator rod ends are installed, repetitive LPIs of the left and right MLG retract actuator rod ends, and replacement of left and right MLG retract actuator rod ends. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because fatigue cracking of the left and right MLG retract actuator rod ends could lead to left or right MLG collapse. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Interim Action

We consider this AD interim action. We are currently considering requiring the replacement of affected left and right MLG retract actuator rod ends with P/N P3A6460, which will constitute terminating action for the inspections required by this AD. However, the planned compliance time for the replacement would allow enough time to provide notice and opportunity for prior public comment on the merits of the replacement.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–7422; Directorate Identifier 2016–NM–079–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Costs of Compliance

We estimate that this AD affects 52 airplanes of U.S. registry.

We also estimate that it will take about 1 work-hour per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be $4,420, or $85 per product.

In addition, we estimate that any necessary follow-on actions will take about 3 work-hours and require parts costing $2,019, for a cost of $2,274 per product. We have no way of determining the number of aircraft that might need these actions.

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–13–14 Bombardier, Inc.: Amendment 39–18579. Docket No. FAA–2016–7422; Directorate Identifier 2016–NM–079–AD.

(a) Effective Date

This AD becomes effective July 20, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model DHC–8–400, –401 and –402 airplanes, certificated in any category, serial numbers 4001, and 4003 through 4325 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by a report of cracked main landing gear (MLG) retract actuator rod ends. We are issuing this AD to detect and correct fatigue cracking of the left and right MLG retract actuator rod ends, which could lead to left or right MLG collapse.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Part Number Inspection

Within 100 flight cycles after the effective date of this AD, inspect the left and right MLG retract actuator rod ends to determine if part number (P/N) P3A2750 or P3A2750–1 is installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number can be conclusively determined from that review.

(h) Repetitive Liquid Penetrant Inspections (LPIs)

For each left or right MLG retract actuator rod end having P/N P3A2750 or P3A2750–1: At the applicable time specified in paragraph (h)(1) or (h)(2) of this AD, do an LPI to detect cracks of the MLG retract actuator rod end, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD. Thereafter, repeat the LPI at intervals not to exceed 600 flight cycles.

(1) If the MLG retract actuator rod end has accumulated more than 6,000 flight cycles as of the effective date of this AD: Inspect within 100 flight cycles after the effective date of this AD.

(2) If the MLG retract actuator rod end has accumulated 6,000 flight cycles or fewer as of the effective date of this AD: Inspect within 600 flight cycles after the effective date of this AD.

(i) Corrective Action

If any crack is found during any inspection required by paragraph (h) of this AD, before further flight replace the cracked MLG retract actuator rod end, P/N P3A2750 or P3A2750–1, with a MLG retract actuator rod end, P/N P3A6460 in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD.

(j) Optional Replacement

Replacement of the left and right side MLG retract actuator rod ends, P/N P3A2750 or P3A2750–1, with left and right MLG retract actuator rod ends, P/N P3A6460, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD, constitutes terminating action for the actions required by paragraphs (g) and (h) of this AD for that airplane.

(k) Exception to Paragraphs (h), (i), and (j) of This AD

If it is not possible to complete all the instructions in Bombardier Service Bulletin 84–32–142, dated May 4, 2016 because of the configuration of the airplane: Before further flight, repair using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

(l) Parts Installation Prohibition

As of the effective date of this AD, no person may install a left or right MLG retract actuator rod end, P/N P3A2750 or P3A2750–1, on any airplane.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO, ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(n) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2016–16, dated May 20, 2016, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–7422.

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Bombardier Service Bulletin 84–32–142, dated May 4, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone: 416–375–4000; fax: 416–375–4539; email: *thd.qseries@aero.bombardier.com;* Internet: *http://www.bombardier.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on June 22, 2016.

Dorr M. Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–15357 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3628; Directorate Identifier 2015–NM–025–AD; Amendment 39–18574; AD 2016–13–10]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2012–12–04, for certain The Boeing Company Model 737–300, –400, and –500 series airplanes. AD 2012–12–04 required repetitive external detailed inspections and nondestructive inspections to detect cracks in the fuselage skin along the chem-mill steps at stringers S–1 and S–2R, between station (STA) 400 and STA 460, and repair if necessary. This new AD requires a preventive modification of the fuselage skin at crown stringers S–1 and S–2R. This new AD also reduces the inspection threshold for certain airplanes. This AD was prompted by a determination that, for certain airplanes, the skin pockets adjacent to the Air Traffic Control (ATC) antenna are susceptible to widespread fatigue damage. We are issuing this AD to detect and correct fatigue cracking of the fuselage skin panels at the chem-mill steps, which could result in sudden fracture and failure of the fuselage skin panels, and consequent rapid decompression of the airplane.

DATES: This AD is effective August 9, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 9, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of July 23, 2012 (77 FR 36134, June 18, 2012).

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com*. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3628.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov.* by searching for and locating Docket No. FAA–2015–3628; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jennifer Tsakoumakis, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5264; fax: 562–627–5210; email: *jennifer.tsakoumakis@faa.gov*.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2012–12–04, Amendment 39–17083 (77 FR 36134, June 18, 2012) (“AD 2012–12–04”). AD 2012–12–04 applied to certain The Boeing Company Model 737–300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on September 14, 2015 (80 FR 55045) (“the NPRM”). The NPRM was prompted by a determination that, for certain airplanes, the skin pockets adjacent to the ATC antenna are susceptible to widespread fatigue damage. The NPRM proposed to continue to require repetitive external detailed inspections and nondestructive inspections to detect cracks in the fuselage skin along the chem-mill steps at stringers S–1 and S–2R, between STA 400 and STA 460, and repair if necessary. The NPRM also proposed to require a preventive modification of the fuselage skin at crown stringers S–1 and S–2R. In addition, the NPRM proposed to revise certain compliance times. We are issuing this AD to detect and correct fatigue cracking of the fuselage skin panels at the chem-mill steps, which could result in sudden fracture and failure of the fuselage skin panels, and consequent rapid decompression of the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA’s response to each comment.

Requests To Clarify Compliance Time Changes

Boeing asked that we change the NPRM preamble, which stated that the proposed AD would reduce the inspection thresholds “and repetitive intervals” for certain airplanes. Boeing stated that the repetitive inspection intervals specified in Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, remain unchanged from the previous version of the service information, which was mandated by AD 2012–12–04. Boeing added that Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, reduced only the inspection threshold for those airplanes.

We agree with the commenter’s request for the reason provided. We have changed the language in the **SUMMARY** of this final rule accordingly.

Request To Clarify Acceptable Previous Alternative Methods of Compliance (AMOCs)

Boeing and Southwest Airlines (SWA) asked that we revise paragraph (l)(4) of the proposed AD. Boeing requested that we state that AMOCs approved for AD 2012–12–04 are approved as AMOCs for “all corresponding requirements”—instead of just the requirements of paragraph (g)—of the proposed AD. Boeing stated that this proposed change matches the wording in paragraph (l)(4) of AD 2012–12–04. SWA added that paragraph (l)(4) of the proposed AD does not provide credit for AMOCs approved for the actions specified in paragraphs (f) and (g) of AD 2008–19–03, Amendment 39–15670 (73 FR 56958, October 1, 2008) (“AD 2008–19–03”). (AD 2008–19–03 was superseded by AD 2012–12–04.)

We agree to revise paragraph (n)(4) of this AD (paragraph (l)(4) of the proposed AD) to specify that AMOCs approved for AD 2012–12–04 are approved as AMOCs for all the corresponding provisions of this AD.

It is not necessary, however, to state that AMOCs approved for AD 2008–19–03 are approved for the requirements of this AD. When AD 2008–19–03 was superseded, the corresponding provisions of AD 2008–19–03 were retained in AD 2012–12–04. Therefore, no change to this final rule is necessary in this regard.

Request To Separate Certain Actions for Clarification

Boeing, ASL Airlines France, and SWA asked that we clarify the requirements of paragraph (h) of the proposed AD by separating the actions into two core paragraphs: One paragraph for “Repairs” and one paragraph for the “Preventive Modification.” Boeing stated that tables 1, 2, and 3 of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, address the repair and preventive modification instructions for Group 1 airplanes, and table 5 addresses repair instructions for Group 2 airplanes; therefore table 5 should not be included in paragraph (h)(2) of the proposed AD. Boeing also stated that Note (e) of tables 1, 2, and 3 of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, provides a terminating action provision for the repetitive inspections under the installed preventive modification doubler; therefore a terminating action should be added to paragraph (h)(2) of the proposed AD. ASL Airlines France stated that, as written, paragraph (h) of the proposed AD is confusing because it would require the preventive modification specified in paragraph (h)(2) of the proposed AD to be installed only if cracking is found. SWA stated that Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, does not provide repair instructions for cracks found in four or more tear strap bays and certain other conditions, as specified in figure 6 or figure 8 of the Accomplishment Instructions. SWA asked that a provision be added to paragraph (h)(2) of the proposed AD to allow for both new and existing repairs to remain on the airplane if the repair covers all eight chem-mill step inspection areas between STA 410 and STA 450, if approved by the FAA or a Boeing-approved representative.

We agree with the commenters' requests for the reasons provided. We have separated paragraph (h) of the proposed AD into paragraphs (h) and (i) of this AD to clarify the actions identified by the commenters (and have redesignated subsequent paragraphs accordingly).

Request To Add Exception for the Preventive Modification

Boeing asked that we add a new exception to address the preventive modification. Boeing stated that paragraph (j)(3) of the proposed AD addresses repairs, and a similar paragraph needs to be added to address the preventive modification specified in Part 9 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015; Part 9 specifies contacting Boeing for preventive modification instructions. Boeing added that the new exception should be done using a method approved by the FAA or a Boeing approved representative.

We agree with the commenter's request. Part 9 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, specifies contacting Boeing for modification instructions if an existing repair is installed that was not accomplished in accordance with Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015. We have revised paragraph (l)(3) of this AD (paragraph (j)(3) of the proposed AD) to include the exception to account for the preventive modification.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the supplemental type certificate (STC) ST01219SE does not affect the actions specified in the NPRM.

We agree with the commenter. We have redesignated paragraph (c) of the proposed AD as (c)(1) and added new paragraph (c)(2) to this AD to state that installation of STC ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/BE866B732F6CF31086257B9700692796?OpenDocument&Highlight=st01219se*) does not affect the ability to accomplish the actions required by this final rule. Therefore, for airplanes on which STC ST01219SE is installed, a "change in product" AMOC approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request To Restate the Optional Modification in AD 2012–12–04

Boeing and Al Nippon Airways (ANA) asked that the optional modification specified in paragraph (i) of AD 2012–12–04 be restated in this AD. The commenters stated that Section 1.F., "Approval" of Boeing Alert Service Bulletin 737–53A1305, Revision 1, dated September 19, 2012, includes approval of the accomplishment of the inspections and modifications, in accordance with that service information for the modified area only, as a method of compliance with the modification specified in paragraph (i) of AD 2012–12–04. The commenters added that since the optional modification is not restated in the proposed AD, this approval is now eliminated.

We agree with the commenters for the reasons provided. We have restated the optional modification in new paragraph (j) of this AD (paragraph (i) of AD 2012–12–04), and redesignated subsequent paragraphs accordingly.

Request To Clarify the Extent of AMOC Approvals

Boeing asked whether AMOCs would be considered for "preventive modifications," in addition to repairs, in paragraph (l)(3) of the proposed AD. Boeing stated that adding this would address the AMOC requirement for the mandatory preventive modification.

We agree with the commenter's request because deviations to the mandated preventive modification are possible. Therefore, we have added "modification" (as well as "alteration") to paragraph (n)(3) of this AD (paragraph (l)(3) of the proposed AD).

Request To Clarify Exception

ASL Airlines France asked that we clarify the reference in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, specified in the "Condition" columns. The commenter stated that the flight-cycle compliance time referred to in these columns specifies "at the Revision 3 date of this service bulletin" instead of "as of the effective date of this AD." The commenter asked that we include a new paragraph to clarify that "as of the effective date of this AD" should be used for compliance throughout the proposed AD.

We acknowledge the commenter's concern; however, paragraph (l)(1) of the proposed AD already addressed this difference; paragraph (j)(2) of this AD retains this provision. Therefore, no change to this AD is necessary in this regard.

Request To Correct Typographical Errors

Boeing and ASL Airlines France asked that we correct the paragraph reference in Note 1 to paragraph (i) of the proposed AD and in paragraph (j)(3) of the proposed AD. The commenters stated that these are typographical errors.

The information in Note 1 to paragraph (i) of the proposed AD has been included in paragraph (j) of this final rule (paragraph (i) of the proposed AD), therefore "Note 1" no longer exists. In light of this, the requested correction is not necessary in this regard. We have corrected the reference in paragraph (j)(3) of the proposed AD (paragraph (l)(3) of this AD) accordingly.

Change to Paragraph (k) of This AD

We have revised the language in paragraph (k) of this AD (paragraph (i) in the proposed AD) to clarify that the post-repair/post-modification inspections are airworthiness limitations that are required by maintenance and operational rules; therefore, these inspections are not required by this AD.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015. The service information describes procedures for repetitive external detailed inspections and non-destructive inspections to detect cracks in the fuselage skin along the chem-mill steps at stringers S–1 and S–2R, between STA 400 and STA 460, and repair of any cracking. The service information also describes procedures for a modification of the chem-mill steps at the locations identified, including related investigative actions and corrective actions, and repetitive post-mod inspections. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 186 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained inspections from AD 2012–12–04.	Between 7 and 15 work-hours × $85 per hour, depending on airplane configuration = between $595 and $1,275 per inspection cycle.	$0	Between $595 and $1,275 per inspection cycle.	Between $110,670 and $237,150 per inspection cycle.
New modification	236 work-hours × $85 per hour = $20,060.	[1]	$20,060	$3,731,160.

[1] We currently have no specific cost estimates associated with the parts necessary for the modification. We cannot determine the cost of the materials because the modification parts must be sized at the time the modification is installed, taking into account any existing repairs in the area.

We have received no definitive data that enables us to provide a cost estimate for the on-condition actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2012–12–04, Amendment 39–17083 (77 FR 36134, June 18, 2012), and adding the following new AD:

2016–13–10 The Boeing Company: Amendment 39–18574; Docket No. FAA–2015–3628; Directorate Identifier 2015–NM–025–AD.

(a) Effective Date

This AD is effective August 9, 2016.

(b) Affected ADs

This AD replaces AD 2012–12–04, Amendment 39–17083 (77 FR 36134, June 18, 2012) ("AD 2012–12–04").

(c) Applicability

(1) This AD applies to The Boeing Company Model 737–300, –400, and –500 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/BE866B732F6CF31086257B9700692796?OpenDocument&Highlight=st01219se*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a "change in product" alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of cracks found on the fuselage skin at the chem-mill steps, and the determination that, for certain airplanes, the skin pockets adjacent to the Air Traffic Control antenna are susceptible to widespread fatigue damage. We are issuing this AD to detect and correct fatigue cracking of the fuselage skin panels at the chem-mill steps, which could result in sudden fracture and failure of the fuselage skin panels, and consequent rapid decompression of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspections

At the applicable time specified in tables 1, 2, 3, and 5 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, except as required by paragraphs (l)(1) and (l)(2) of this AD: Do the actions specified in paragraphs (g)(1) and (g)(2) of this AD, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, except as required by paragraph (l)(3) of this AD. Repeat the applicable inspections thereafter at the applicable times specified in paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015.

(1) Do an external detailed inspection for cracking of the fuselage skin chem-mill steps.

(2) Do an external non-destructive (medium frequency eddy current, magneto optical imaging, C-Scan, or ultrasonic phased array) inspection for cracking of the fuselage skin chem-mill steps.

(h) Repair

If any cracking is found during any inspection required by paragraph (g) of this AD, do the applicable actions specified in paragraph (h)(1), (h)(2), or (h)(3) of this AD.

(1) Repair before further flight in accordance with Part 2 (for Group 1 airplanes) or Part 7 (for Group 2 airplanes) of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015; except as required by paragraph (l)(3) of this AD. Installation of a repair that meets the conditions specified in Note (a) of table 1, 2, 3, or 5 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, terminates the repetitive inspections required by paragraph (g) of this AD for the area covered by that repair only.

(2) For Group 1 airplanes: Accomplishing the modification specified in paragraph (i) of this AD is a method of compliance with paragraph (h)(1) of this AD.

(3) If any cracking is found in any area not covered by the preventive modification doubler during any inspection required by paragraph (g) of this AD: Repair before further flight, in accordance with Part 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, except as provided by paragraph (n)(4) of this AD. Both new and existing repairs are allowed if the repair covers all eight chem-mill step inspection areas between STA 410 and STA 450, and the repairs were done using a method approved in accordance with the procedures specified in paragraph (n)(1) of this AD.

(i) Preventive Modification

For Group 1 airplanes: At the applicable time specified in tables 1, 2 and 3 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, except as required by paragraphs (l)(1) and (l)(2) of this AD, do a preventive modification of the fuselage skin at crown stringers S–1 and S–2R, including all applicable related investigative actions in accordance with Part 9 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, except as provided by paragraph (n)(4) of this AD. Do all applicable related investigative actions concurrently with the modification. Installation of a preventive modification terminates the repetitive inspections required by paragraph (g) of this AD for the modified area only. Thereafter, repeat the inspections specified in Part 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015.

(j) Optional Modification

Accomplishing a modification of the chem-mill steps at any location identified in Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, using a method approved in accordance with the procedures specified in paragraph (n)(1) of this AD, terminates the repetitive inspections required by paragraph (g) of this AD for the modified area only.

(k) Post-Repair/Post-Modification Inspections

Tables 4 and 6 of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, specify post-repair/post-modification airworthiness limitation inspections in compliance with 14 CFR 25.571(a)(3) at the modified locations, which support compliance with 14 CFR 121.1109(c)(2) or 129.109(b)(2). As airworthiness limitations, these inspections are required by maintenance and operational rules. It is therefore unnecessary to mandate them in this AD. Deviations from these inspections require FAA approval, but do not require an alternative method of compliance.

(l) Exceptions to Service Bulletin Specifications

(1) Where Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, specifies a compliance time "after the Revision 3 date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where the Condition column of paragraph 1.E., "Compliance," of Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, specifies a condition based on when an airplane has or has not been inspected, this AD bases the condition on whether an airplane has or has not been inspected on the effective date of this AD.

(3) Where Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015, specifies to contact Boeing for repair or preventive modification instructions: Before further flight, do the repair or preventive modification, as applicable, using a method approved in accordance with the procedures specified in paragraph (n)(1) of this AD.

(m) Credit for Previous Actions

(1) This paragraph provides credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before July 23, 2012 (the effective date of AD 2012–12–04), using Boeing Alert Service Bulletin 737–53A1293, Revision 1, dated July 7, 2010, which is not incorporated by reference in this AD.

(2) This paragraph provides credit for actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011, which was incorporated by reference in AD 2012–12–04.

(n) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (o)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation method must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2012–12–04 are approved as AMOCs for the corresponding provisions of this AD.

(o) Related Information

(1) For more information about this AD, contact Jennifer Tsakoumakis, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5264; fax: 562–627–5210; email: *jennifer.tsakoumakis@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(5) and (p)(6) of this AD.

(p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on August 9, 2016.

(i) Boeing Alert Service Bulletin 737–53A1293, Revision 3, dated January 23, 2015.

(ii) Reserved.

(4) The following service information was approved for IBR on July 23, 2012 (77 FR 36134, June 18, 2012).

(i) Boeing Service Bulletin 737–53A1293, Revision 2, dated August 10, 2011.

(ii) Reserved.

(5) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on June 21, 2016.

Dorr Anderson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–15291 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9766]

RIN 1545–BM87

Self-Employment Tax Treatment of Partners in a Partnership That Owns a Disregarded Entity; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; correcting amendment.

SUMMARY: This document contains a correction to final and temporary regulations (TD 9766) that were published in the **Federal Register** on May 4, 2016 (81 FR 26693). The final and temporary regulations clarify the employment tax treatment of partners in a partnership that owns a disregarded entity.

DATES: This correction is effective on July 5, 2016 and applicable on May 4, 2016.

FOR FURTHER INFORMATION CONTACT: Andrew Holubeck at (202) 317–4774 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9766) that are the subject of this correction are under section 7701 of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9766) contains an error that may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 301 is corrected by making the following correcting amendment:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 301.7701–2T is amended by revising paragraph (e)(8)(ii) to read as follows:

§ 301.7701–2T Business entities; definitions (temporary).

* * * * *

(e) * * *

(8) * * *

(ii) *Expiration date.* The applicability of paragraph (c)(2)(iv)(C)(*2*) of this section expires on or before May 3, 2019, or such earlier date as may be determined under amendments to the regulations issued after May 3, 2016.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2016–15739 Filed 7–1–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0169]

RIN 1625–AA08

Special Local Regulation; Cumberland River, Mile 190.0 to 191.5; Nashville, TN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for all waters of the Cumberland River beginning at mile marker 190.0 and ending at mile marker 191.5 from 9 a.m. until noon on July 30, 2016. This special regulation is necessary to provide safety for the participants in the "Music City SUP Race" marine event. This rulemaking prohibits persons and vessels from being in the special local regulated area unless authorized by the Captain of the Port Ohio Valley or a designated representative.

DATES: This rule is effective from 9 a.m. until noon on July 30, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0169 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Ashley Schad, MSD Nashville, Nashville, TN, at 615–736–5421 or at *Ashley.M.Schad@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

On January 28, 2016, the Nashville Paddle Company notified the Coast Guard that it will be conducting a rowing race from 9 a.m. to noon on July 30, 2016. The event will consist of at least 75 participants on various sized stand up paddle boards and kayaks on the Cumberland River. The Captain of the Port Ohio Valley (COTP) determined that additional safety measures are necessary to protect participants, spectators, and waterway users during this event. In response, on June 10, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) Special Local Regulation; Cumberland River, Mile 190.0 to 191.5; Nashville, TN (81 FR 37562).

There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this marine event. During the comment period that ended June 27, 2016 we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Ohio Valley (COTP) has determined that potential hazards associated with the marine event in this July 30, 2016, event will be a safety concern for the participants of the event. The purpose of this rule is to ensure safety of vessels and participants and the navigable waters in the special local regulation area before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published May 15, 2016. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM other than providing the final enforcement times and date.

This rule establishes a special local regulation for all waters of the Cumberland River beginning at mile marker 190.0 and ending at mile marker 191.5 from 9 a.m. until noon on July 30, 2016. The duration of the regulated area is intended to ensure the safety of vessels and participants and these navigable waters before, during, and after the scheduled 9 a.m. to noon marine event. No vessel or person will be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the special local regulation. This rule restricts transit on the Cumberland River from mile 190.0 to 191.5, for a short duration of 3 hours on one day; Broadcast Notice to Mariners and Local Notices to Mariners will also inform the community of this special local regulation so that they may plan accordingly for this short restriction on transit. Vessel traffic may request permission from the COTP Ohio Valley or a designated representative to enter the restricted area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the special local regulated area may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulated area lasting 3 hours that will prohibit entry within the regulated area. It is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERWAYS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.35T08–0169 to read as follows:

§ 100.35T08–0169 Special Local Regulation; Cumberland River Mile 190.0 to Mile 191.5; Nashville, TN.

(a) *Location.* All waters of the Cumberland River beginning at mile marker 190.0 and ending at mile marker 191.5 at Nashville, TN.

(b) *Enforcement period.* This special local regulation will be enforced from 9 a.m. until noon on July 30, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in § 100.801 of this part, entry into this area is prohibited unless authorized by the Captain of the Port Ohio Valley or a designated representative.

(2) Persons or vessels requiring entry into or passage through the area must request permission from the Captain of the Port Ohio Valley or a designated representative. U. S. Coast Guard Sector Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465.

Dated: June 28, 2016.

R. V. Timme,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–15741 Filed 7–1–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2016–0278 FRL–9948–60–Region 6]

Approval and Promulgation of Implementation Plans; Louisiana; Baton Rouge Nonattainment Area; Base Year Emissions Inventory for the 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the State Implementation Plan (SIP) submitted by the Louisiana Department of Environmental Quality (LDEQ) to address the emissions inventory (EI) requirement for the Baton Rouge ozone nonattainment area (BRNA) for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS). The Clean Air Act (CAA) requires an EI for all ozone nonattainment areas. The inventory includes emission data for Nitrogen Oxides (NO_X) and Volatile Organic Compounds (VOCs). EPA is approving the revisions pursuant to section 110 and part D of the CAA and EPA's regulations.

DATES: This rule is effective on September 6, 2016 without further notice, unless the EPA receives relevant adverse comment by August 4, 2016. If the EPA receives such comment, the EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2016–0278, at *http://www.regulations.gov* or via email to *salem.nevine@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact Ms. Nevine Salem, 214–665–7222, *salem.nevine@epa.gov.* For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Nevine Salem, 214–665–7222, *salem.nevine@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Ms. Salem or Mr. Bill Deese at 214–665–7253.

SUPPLEMENTARY INFORMATION: Throughout this document wherever "we," "us," or "our" is used, we mean the EPA.

I. Background

A. The 2008 Ozone National Ambient Air Quality Standards (NAAQS) and Emissions Inventory Requirements

On March 12, 2008 EPA revised the eight-hour ozone NAAQS from 0.08 part per million (ppm) to 0.075 ppm. (73 FR 16436, March 27, 2008). In 2012, EPA designated nonattainment areas for the 2008 ozone NAAQS (2008 ozone nonattainment areas) (77 FR 30088, May 21, 2012).[1] The Baton Rouge area was designated as nonattainment areas for the 2008 ozone NAAQS. The BRNA consists of five parishes: Ascension, East Baton Rouge, Iberville, Livingston, and West Baton Rouge.

CAA sections 172(c)(3) and 182(a)(1), require states to develop and submit, as a SIP revision, an EI for all areas designated as nonattainment for the ozone NAAQS. An EI is an estimation of actual emissions of air pollutants in an area. Ground-level ozone, O_3, is a gas that is formed by the reaction of volatile organic compounds (VOCs) and oxides of nitrogen (NO_X) in the atmosphere in the presence of sunlight. (VOCs and NO_X are referred to as ozone precursors). Therefore, an EI for ozone covers the emissions of VOC and NO_X. These precursor emissions are emitted by many types of pollution sources, including power plants and industrial emissions sources, on-road and off-road motor vehicles and engines, smaller stationary sources, collectively referred to as nonpoint sources, and biogenic sources.[2] The EI provides emissions data for a variety of air quality planning tasks including establishing baseline emission levels, calculating federally required emission reduction targets needed to attain the NAAQS, determining emission inputs for ozone air quality simulation models, and tracking emissions over time to determine progress toward achieving air quality and emission reduction goals.

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[1] On October 1, 2015, the EPA strengthened the ozone standard to 0.070 ppm (80 FR 65292, October 26, 2015). The EPA has not made area designations under this new standard and the emissions inventory under evaluation in this rulemaking does not address that standard.

[2] Biogenic emissions are produced by living organisms and are typically not included in the base year emission inventories, but are considered in ozone modeling analyses, which must consider all emissions in a modeled area.

As stated above, the CAA requires the states to submit EIs for areas designated as nonattainment for ozone. For the 2008 ozone NAAQS, EPA has recommended that states use 2011 as a base year for the emission estimates (78 FR 34178, 34190, June 6, 2013). However, EPA also allows states to submit base year emissions for other years during a recent ozone standard violation period. States are required to submit estimates of VOC and NO_X emissions for four general classes of anthropogenic sources: stationary point sources; nonpoint sources; on-road mobile sources; and off-road mobile sources in their EIs.

B. Louisiana's Submittal

In a letter dated May 2, 2016, the LDEQ submitted the 2011 base year inventory to the EPA as part of the BRNA designation and maintenance plan. The EPA reviewed the 2011 base year inventory and determined that it was developed in accordance with EPA guidelines. Table 1 summarizes the 2011 VOC and NO_X base year emission for the BRNA area for a typical summer day (reflective of the summer period, when the highest ozone concentrations are expected in these ozone nonattainment areas).

TABLE 1—BATON ROUGE NONATTAINMENT AREA 2011 VOC AND NO_X BASELINE EMISSIONS INVENTORY

[Tons/Day]

Source type	NO_X	VOC
Point	74.2	33.6
Nonpoint	17.1	82.6
Onroad Mobile	38.4	19.2
Nonroad Mobile	27.3	8.7
Total	157.0	144.0

C. CAA Requirements for the SIP Revision

The primary CAA requirements pertaining to the SIP revision submitted by LDEQ are found in CAA sections 110(l), 172(c)(3) and 182(a)(1). CAA section 110(l) requires that a SIP revision submitted to EPA be adopted by the State after reasonable notice and public hearing. Section 110(l) also prevents us from approving a SIP revision if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA. CAA sections 172(c)(3) and 182(a) requires a SIP revision that is a comprehensive, accurate, current inventory of actual emissions from all sources.

II. EPA's Evaluation

EPA has reviewed the revision for the consistency with the requirements of EPA regulations. A summary of EPA's analysis is provided below. For a full discussion of our evaluation, please see our TSD.

CAA sections 172 (c)(3) and 182(a)(1) require an inventory of actual emissions from all sources of relevant pollutants in the nonattainment areas. EPA specified in the 2008 ozone standard SIP requirements rule that the states should use 2011 as a base year for EI SIPs to address the EI requirements. LDEQ has developed a 2011 base year emissions inventory for the Baton Rouge nonattainment areas. The 2011 base year emissions includes all point, nonpoint, non-road mobile, and on-road mobile source emissions in BRNA. LDEQ utilized data from the US EPA 2011 National Emissions Inventory (NEI), Version 2 as the baseline emissions inventory to identify the level of emissions in the area during the period of monitored attainment and satisfy the requirement of section 182(a)(1).

EPA reviewed the emission inventory and determined that it is approvable because it was developed in accordance with EPA guidance on emission inventory preparation. The inventory is a comprehensive, accurate, and current inventory of actual emissions for all relevant sources in accordance with CAA sections 172(c)(3) and 182(a)(1). Additionally we found that (1) LDEQ adopted after reasonable notice and public hearing and (2) approval would not interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable requirement of the CAA. A technical support document (TSD) was prepared which details our evaluation. Our TSD may be accessed online at *www.regulations.gov,* Docket No. EPA–R06–OAR–2016–0278.

III. Final Action

We are approving a Louisiana SIP revision submitted to address the emissions inventory requirement for the Baton Rouge 2008 ozone NAAQS nonattainment area. The inventory we are proposing to approve is listed in table 1 above.

We are publishing this rule without prior proposal because we view this as a non-controversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if relevant adverse comments are received. This rule will be effective on September 6, 2016 without further notice unless we receive relevant adverse comment by August 4, 2016. If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so now. Please note that if we receive relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: June 22, 2016.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart T—Louisiana

■ 2. In § 52.970, the second table in paragraph (e) is amended by adding the entry "2011 Emissions Inventory for the 2008 Ozone NAAQS" at the end of the table to read as follows:

§ 52.970 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED LOUISIANA NON-REGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA Approval date	Explanation
*	*	*	*	*
2011 Emissions Inventory for the 2008 Ozone NAAQS.	Baton Rouge Ozone Nonattainment Area.	5/2/16	7/5/16 [INSERT **Federal Register** CITATION].	

[FR Doc. 2016–15748 Filed 7–1–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA–HQ–OW–2015–0668; FRL–9948–62–OW]

Decision Not To Regulate Forest Road Discharges Under the Clean Water Act; Notice of Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Decision.

SUMMARY: The Environmental Protection Agency (EPA) is providing notice of the Agency's decision that no additional regulations are needed to address stormwater discharges from forest roads under Section 402(p)(6) of the Clean Water Act (CWA) at this time. This document responds to the remand in *Environmental Defense Center, Inc.* v. *U.S. EPA*, 344 F.2d 832 (9th Cir. 2003) that requires EPA to consider whether the CWA requires the Agency to regulate stormwater discharges from forest roads.

DATES: This decision shall be considered issued for purposes of judicial review at 1 p.m. Eastern time on July 11, 2016.

FOR FURTHER INFORMATION CONTACT: Prasad Chumble, EPA Headquarters, Office of Water, Office of Wastewater Management via email at *chumble.prasad@epa.gov* or telephone at 202–564–0021.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Applicability

This document does not impose requirements on any entity.

B. Obtaining Copies of This Document and Related Information

1. Docket

EPA has established a docket for this action under Docket ID No. [EPA–HQ–OW–2015–0668; FRL–9948–62–OW]. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the Docket Center is (202) 566–1744.

2. Electronic Access

You may access this **Federal Register** document electronically from the Government Printing Office under the "**Federal Register**" listings at FDSys (*http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR*).

3. Dates

In accordance with 40 CFR part 23, this decision shall be considered issued for purposes of judicial review at 1 p.m. Eastern time on July 11, 2016. Under Section 509(b)(1) of the CWA, judicial review of this decision can be had only by filing a petition for review in the U.S. Court of Appeals within 120 days after the decision is considered issued for purposes of judicial review.

II. Executive Summary

EPA has determined not to designate stormwater discharges from forest roads for regulation under Section 402(p)(6) of the Clean Water Act (CWA) at this time. EPA's decision is based on several interrelated factors. First, state, federal, regional, tribal government, and private sector programs already exist nationwide to address water quality problems caused by discharges from forest roads. Many of these programs have been improved and updated in recent years. Program implementation rates are generally high and have been shown to be effective in protecting water quality when properly implemented. These programs employ a variety of approaches, based in part on variations in regional topography and climate. While EPA recognizes that existing programs vary in their degree of rigor, the Agency has concluded that efforts to help strengthen existing programs would be more effective in further addressing forest road discharges than superimposing an additional federal regulatory layer over them.

Some commenters have asserted that federal regulatory requirements could, in theory, promote national consistency and improvements in less effective programs. In practice, however, federal forest roads regulation presents a number of challenges that make achievement of that result unlikely. Wide variations in topography, climate, ownership, management, and use across the nation's network of forest roads make the establishment of any nationwide regulatory program a complex and difficult endeavor. Mechanisms for implementation and enforcement of any federal regulatory requirements are limited, as recent amendments to CWA Section 402(*l*) preclude both the use of National Pollutant Discharge Elimination System (NPDES) permits to regulate most discharges from forest roads and citizen suit enforcement of any Section 402(p)(6) requirements. Some commenters discussed the failings of existing best management practices (BMP) programs, including insufficient compliance rates and compliance monitoring, but a federal EPA-administered program would not necessarily be able to address these challenges more effectively than entities with regional expertise overseeing existing forestry management practice programs, especially without the accountability mechanisms afforded by a permitting program or third-party enforcement.

For these reasons, elaborated upon below, EPA is exercising the "broad discretion the CWA gives the EPA in the realm of stormwater runoff," in deciding not to regulate stormwater discharges from forest roads. *See Decker* v. *Nw. Envtl. Def. Ctr.*, 133 S. Ct 1326, 1338 (2013) (affirming EPA's determination not to regulate stormwater discharges from logging roads in its industrial stormwater rule). Instead, EPA intends to work in consultation with state and local officials, as well as other federal agencies and interested stakeholders, to help strengthen their existing programs and improve awareness and implementation of forestry best management practices. In reaching this conclusion, the Agency is cognizant that the CWA reserves for states "the primary responsibilities and rights . . . to prevent, reduce, and eliminate pollution [and] to plan the development and use (including restoration, preservation, and enhancement) of land and water resources . . ." 33. U.S.C. 1251(b).

III. Legal Background

The objective of the CWA is to restore and maintain the chemical, physical, and biological integrity of the nation's waters. 33 U.S.C. 1251(a). To that end, the CWA provides that the discharge of any pollutant by any person shall be unlawful, except in compliance with other provisions of the statute. The CWA provides for a permit program, in general, for the discharge of a pollutant from a "point source," which is defined in Section 502 of the CWA as "any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged." 33 U.S.C. 1362(14). In 1987 Congress added Section 402(p) to the CWA, which required NPDES permits for certain specified stormwater discharges and provided EPA with discretion to determine whether and how discharges from other stormwater sources should be addressed "to protect water quality." *See Northwest Environmental Advocates* v. *EPA*, 640 F.3d 1063, 1083 (9th Cir. 2011) ("[i]t is within the discretion of EPA to promulgate Phase II regulations requiring, or not requiring, permits for such discharges").

For the initial phase of stormwater regulation, Section 402(p)(1) created a temporary moratorium on NPDES permits for point sources except for those listed in Section 402(p)(2). Section 402(p)(2) includes discharges already required to have a permit; discharges from municipal separate storm sewer systems serving a population of 100,000 or more; and stormwater discharges "associated with industrial activity." Congress did not define discharges associated with industrial activity, allowing EPA to interpret the term. For other stormwater discharges, Section 402(p)(5) directs EPA to conduct studies, in consultation with the states, for "identifying those stormwater discharges or classes of stormwater discharges for which permits are not required"; "determining to the maximum extent practicable, the nature and extent of pollutants in such discharges"; and "establishing procedures and methods to control stormwater discharges to the extent necessary to mitigate impacts on water quality."

Section 402(p)(6) authorizes the Administrator to issue regulations, in consultation with state and local officials, based on the studies prescribed by Section 402(p)(5). It provides EPA discretion in selecting which discharge sources to regulate and how to regulate them; it does not require the use of NPDES permits. Specifically, the section states that the regulations "shall establish priorities, establish requirements for state stormwater management programs, and establish expeditious deadlines" and may include "performance standards, guidelines, guidance, and management practices and treatment requirements, as appropriate." 33 U.S.C. 1342(p)(6). This flexibility is unique to stormwater discharges regulated under Section 402(p)(6) and differs from the requirement for NPDES permits for stormwater discharges listed in Section 402(p)(2) of the Act.

In 1990, EPA promulgated the Phase I stormwater regulations (55 FR 47990, November 16, 1990) ("Phase I Rule"), following the 1987 CWA amendments which directed the Agency to develop regulations requiring permits for large and medium municipal separate storm sewer systems and stormwater "discharges associated with industrial activity." In March 1995, EPA submitted to Congress a report on the results of the Section 402(p)(5) study that evaluated the nature of stormwater discharges from municipal and industrial facilities not already regulated under the Phase I regulations (EPA, 1995). On December 8, 1999, EPA promulgated the Phase II stormwater regulations to address stormwater discharges from small municipal separate storm sewer systems and construction sites that disturb one to five acres. 64 FR 68722. Under CWA Sections 402(p)(2)(E) and 402(p)(6), EPA retains the discretionary authority to designate additional stormwater discharges for regulation.

The Phase II stormwater regulations were challenged in *Environmental Defense Center* v. *US EPA,* 344 F.3d 832 (9th Cir. 2003) (*EDC* v. *EPA*). In that case, petitioners contended that EPA arbitrarily failed to regulate discharges from forest roads under the Phase II rule. The court held that EPA failed to consider petitioners' comments and remanded the issue to EPA "so that it may consider in an appropriate proceeding Petitioner's contention that Section 402(p)(6) requires the EPA to regulate forest roads. The EPA may then either accept Petitioners' arguments in whole or in part, or reject them on the basis of valid reasons that are adequately set forth to permit judicial review." *Id.* at 863.

In the years following the decision in *EDC* v. *EPA,* EPA undertook research to improve the Agency's knowledge of the water quality impacts of forest road stormwater discharges and the programs that exist to reduce those impacts. During that period, the Northwest Environmental Defense Center initiated litigation concerning logging road stormwater discharges. In 2011, the U.S. Court of Appeals for the Ninth Circuit issued a decision in *Northwest Environmental Defense Center* v. *Brown,* 640 F.3d 1063 (9th Cir. 2011) ("*NEDC*"), a citizen suit alleging violations of the CWA for unpermitted discharges of stormwater from ditches alongside two logging roads in state forests. The court held that because the stormwater runoff from the two roads in question is collected by a system of ditches, culverts, and channels and then discharged into waters of the U.S., there was a point source discharge of stormwater associated with industrial activity for which an NPDES permit is required.

On May 23, 2012, EPA published a Notice in the **Federal Register** summarizing known water quality impacts related to forest roads and discussing existing state, tribal, and voluntary programs designed to address those impacts. (77 FR 30473). The Notice expressed EPA's intent to specify that only stormwater discharges associated with rock crushing, gravel washing, log sorting, and log storage are discharges associated with silvicultural activity that are subject to permitting under the stormwater regulations pertaining to industrial activity. The Notice also discussed the Agency's consideration of non-permitting approaches to address other stormwater discharges from forest roads. On December 7, 2012, EPA promulgated a rule (77 FR 72970) clarifying that discharges of stormwater from silviculture activities other than rock crushing, gravel washing, log sorting, and log storage do not require an NPDES permit. On March 20, 2013, the Supreme Court reversed the Ninth Circuit's ruling in *NEDC,* holding that discharges of stormwater that ran off logging roads into ditches, culverts, and channels did not require an NPDES permit as stormwater from industrial activity. *See Decker* v. *Nw. Envtl. Def. Ctr.,* 133 S. Ct 1326 (2013).

In January 2014, Congress amended CWA Section 402(*l*) to effectively prohibit the requirement of NPDES permits for the discharge of runoff "resulting from the conduct of the following silviculture activities conducted in accordance with standard industry practice: nursery operations, site preparation, reforestation and subsequent cultural treatment, thinning, prescribed burning, pest and fire control, harvesting operations, surface drainage, or road construction and maintenance." 33 U.S.C. 1342(l). In addition, the amendment prohibits third-party lawsuits ("citizen suits") authorized by CWA Section 505(a) for any requirements established under Section 402(p)(6) for the silviculture activities listed above.

In December 2014, EDC and the Natural Resources Defense Council filed a petition with the Ninth Circuit to compel EPA to respond, within six months, to the question remanded in the 2003 *EDC* v. *EPA* decision of whether Section 402(p)(6) requires federal regulation of stormwater discharges from forest roads. Following execution of a settlement agreement filed with the court on August 26, 2015, the court entered an order establishing a schedule requiring EPA to issue a final determination by May 26, 2016. The parties subsequently extended the deadline by joint stipulation to June 27, 2016.

IV. Background on Forest Roads and Their Water Quality Impacts

Forests cover about one-third of the continental U.S. (approximately 816 million acres). Over half are privately owned (58% or approximately 475 million acres) (USFS, 2016). Of private forest land, 63% is owned by families and individuals and is commonly referred to as "family forests." Most of the family forest owners (around 62%) own fewer than 10 acres of forest land. Owners of the remaining private forest land include corporations, Real Estate Investment Trusts (REITs), conservation organizations, clubs, and Native American tribes (USFS, 2016). Over 300 Native American reservations are significantly forested, and Native American tribal lands include 18.6 million acres of forest land, including 1.5 million acres of productive timberland (Bureau of Indian Affairs, 2009). Private forest land owners invest considerable resources in forest road construction and maintenance, as they are critical assets that enhance property values, maintain economic viability, and facilitate sustainable forestry.

Forty-two percent of forest land, or approximately 341 million acres, is publicly-owned. The federal government administers an estimated 74% of the public forest land. State forestry, park, and wildlife agencies account for most of the 22% of state-owned public forest land. The remaining 4% of public forest land is owned by local governments, such as counties and towns (USFS, 2016). Within the U.S., the distribution of public versus private forests differs greatly among the various regions of the country. For example, forest ownership in the Northwest is dominated by public ownership, primarily by the U.S. Forest Service (USFS) and the Bureau of Land Management (BLM). Private ownership is more prevalent in the Southeast and Northeast (*Id.*).

Forests are connected by a vast network of forest roads built over the course of more than a century. Roads exist in forests for all land ownership categories, enabling activities as varied as timber operations, recreation, fire protection and general transportation. Originally some were built to allow mining or agriculture. The network of forest roads includes both active and inactive roads that vary in age and condition, and which often serve multiple purposes by multiple users at the same time. Because of the nature of timber growing, timber roads are often used just once every fifteen or twenty years. Endicott (2008) noted that:

> [e]ach forest road network commonly contains a collection of older and newer roads, designed to different standards, for various purposes, and crossing terrain of differing sensitivities. This mosaic of road segments has implications for how the forest road network will interact with the forest watershed, streams, and other downstream aquatic resources.

A single road may be subject to different owners and managers and used for different activities at different points. Often the owner of the road is not the owner of the forest land over which the road travels. For example, a BLM-owned road may pass through private property or a timber company-owned road may pass through a state-owned public forest. The purpose of a road may also change at different points; for example, most of a road may be used for recreation but a small part of it may service a timber operation. Legacy roads pose particular concerns for water quality. Built prior to the adoption of modern BMPs, they may be poorly sited or designed and frequently no owner or operator assumes responsibility for those roads.

As previously discussed in 80 FR 69655–69656 (November 10, 2015) and 77 FR 30476 (May 23, 2012), the Agency's research indicates that improperly designed, constructed, maintained, or decommissioned forest roads can impact water quality. These impacts are variable and may include increased sediment load and changes in stream network hydrology, which can cause physical, biological, and ecological impacts to water quality and aquatic organisms.

Erosion from many forest roads does not affect water quality. First, roads that are not hydrologically connected to a stream do not deliver sediment to water bodies. For example, Dube *et al.* (2010), found that in an inventory of forest roads in 60 random four-square-mile sections of forests in the Washington State, only 11% were connected to streams; Skaugset and Allen (1998) surveyed 287 miles of forest roads in 5 regions of Oregon and determined that 25% of forest roads drained directly to streams while another 6% were rated "possible" for sediment delivery. Second, a variety of factors play a role in how water quality is impacted by forest roads, including road design, road surfaces, construction, maintenance, rate of use, topography, soil characteristics, precipitation patterns, and proximity of roads to surface water. The source of water quality impacts tends to be localized.

Available data suggest that the number of surface waters impacted by silvicultural operations, including forest roads, is a small percentage of Section 303(d) listed impaired waters. EPA's analysis of the data shows that this trend has been consistent over time, indicating that water quality impacts appear to have persisted over time, but comprise only a small percentage of all sources of impairment. Specifically, results of nationwide waterbody assessments from the EPA's Assessment and Total Maximum Daily Loads (TMDL) Tracking and Implementation System (ATTAINS),[1] which contains the most currently available data reported by states to the EPA under Sections 305(b) and 303(d) of the CWA, found silviculture, which includes a broad spectrum of forestry activities including regulated activities,[2] contributed to impairment of 40,637 miles of rivers and streams (7% of the total of 614,153 miles impaired) and 159,920 acres of lakes, reservoirs and ponds (1% of the total of 13,009,273 acres of impaired) (ATTAINS 2016). "Forest roads (road construction and use)" or "logging roads" are listed as the "probable source" of impairment for 31,076 miles of rivers and streams (5% of total impaired) and 7,627 acres of lakes, reservoirs and ponds (less than 1% of total impaired).

The extent of the impacts of silvicultural activities on water quality varies by region. Impairment data from states that report probable sources of impairments suggest that forest roads constitute a relatively low percentage of impairments. Examples of states where silviculture (a broader category that includes forest roads) is identified as a probable source of impairment and that document a percentage of the total river and stream miles impaired by 'forest roads' or 'logging roads' include: Idaho (0.62%; forest roads); Kentucky (0.04%; forest roads); Montana (5.71%); New Mexico (1.97%); and Pennsylvania (0.01%) (ATTAINS 2016). Road-related pollutant loading and impairments, however, may represent a higher percentage of impairments within specific regions. For example, within federal lands in the interior Columbia Basin, roads were identified as the largest source of sediment from any land management activity.[3]

EPA recognizes that the national water quality data discussed above have certain limitations. One limitation is that some states, when compiling their Section 305(b) reports, may not report the probable source of an impairment or may list probable impairment sources as unspecified, unknown, or in some other category, which may lead to underreporting of the source of the impairment. Additionally, some states may not assess all of their waters or may use different methodologies to collect or report water quality data, limiting the ability of drawing national-scale conclusions.

ATTAINS data indicating the effect of discharges from forest roads on water quality impairments may therefore not be fully representative due to reporting differences among states. For example, of the 40,637 miles of rivers and streams that ATTAINS indicates are impaired by silviculture, the database shows that California accounts for 34,443, or 85%, nationally (ATTAINS, 2016). Some regions in California use a particular approach toward classifying impairments that increases the reported percentage of impaired miles. Unlike other states, if a given reach of river is identified as impaired for a particular pollutant, some California regions categorize all of the river miles in the entire watershed as impaired.

It is also important to recognize that EPA's data collection methods have changed over time. While ATTAINS compiles state-level data, it relies on the states for this information. The National Water Quality Initiative (NWQI), conducted by EPA, provides very specific information on impairments and sources, but EPA no longer collects these data. EPA currently uses probabilistic approaches (such as the Wadeable Streams Assessment and the National Rivers and Streams Assessment) to collect national-scale data on water quality. While these assessment approaches are sound, they do not reveal specific impairments and causes and therefore are less informative for purposes of this analysis.

Estimating sedimentation specifically related to forest road discharges is also difficult as a practical matter. Unlike industrial and wastewater facilities, which typically have water quality monitoring to provide background data for assessing compliance with water quality standards, there is little to no regular monitoring of water quality in waters affected by forest road discharges. Endicott (2008) noted that "[e]ven a well-designed erosion experiment frequently results in variations from the mean of up to 50%." Investigators may also be unable to differentiate among sediment generated from forest roads and sediment generated from other silvicultural activities, background erosion rates, or other sources. Endicott (2008) further explains that: "Numerous studies have demonstrated that the biotic and chemical "noise" in larger streams renders the water quality effects of forestry activities using BMPs undetectable." Finally, Endicott (2008) recognizes that quantitative data can be difficult to obtain because "impairments can be difficult to detect and/or measure" and "[e]rosion only usually occurs during wet weather."

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[1] *https://iaspub.epa.gov/waters10/attains_index.home*

[2] Non-point source silvicultural activities include nursery operations, site preparation, reforestation and subsequent cultural treatment, thinning, prescribed burning, pest and fire control, harvesting operations, surface drainage in addition to road construction and maintenance from which there is natural runoff at issue here.

[3] *http://www.fs.fed.us/pnw/publications/icbemp.shtml*

V. Role and Effectiveness of Forestry Best Management Practices

The U.S. Forest Service defines Best Management Practices (BMPs) as the following:

> A practice or a combination of practices, that is determined by a State (or designated area-wide planning agency) after problem assessment, examination of alternative practices and appropriate public participation to be the most effective, practical (including technological, economic, and institutional considerations) means of preventing or reducing the amount of pollution generated by nonpoint sources to a level compatible with water quality goals (USFS, 1988).

In the context of forest roads, BMPs focus on preventing and mitigating water quality impacts that may stem from the construction, maintenance and use of forest roads. Forest road BMPs are on the ground activities and structures that, in most cases, aim to prevent discharges of sediment from roads to streams. BMPs may also target other suspended solids, spills and residues, changes in water temperature, and alterations to flow regimes. In some cases they are designed to protect stream geomorphology and habitat for certain species.

BMPs for forest roads generally fall into three categories: BMPs addressing road planning and design, road construction and reconstruction, and road management (*e.g.,* Endicott 2008). Over the past several decades BMPs have been developed, evaluated, and improved based on ongoing research and technical innovation. BMPs are now widely implemented as standard elements of most private, state, and federal forestry programs (Ice *et al.,* 2010). State-specific BMP programs and guidelines are available in most states (NCASI, 2009). Although the primary purpose of BMPs is to reduce environmental impacts, they must also be feasible and practical (Ice, 2004).

BMPs are generally selected based on site-specific needs and conditions, which vary tremendously. Proximity of the road to the stream, size of the road, local geology and climate all influence the occurrence and magnitude of erosion and consequently the types of BMPs that will be most effective. For example, use of gravel to cover a road surface can be a highly effective erosion control BMP in steep terrain. In flat terrain, that same BMP would be less effective and much more expensive than a properly maintained continuous roadside berm (Appelboom *et al.,* 2002).

While BMP design is site-specific, many documents describe the most common BMPs (*e.g.,* NCASI, 2001; EPA, 2005; NCASI, 2009; USFS, 2012; NCASI, 2012). This document does not provide a detailed discussion of the BMPs themselves; a number of comprehensive sources regarding different types of BMPs are available and included in the record for this decision (*e.g.,* NCASI, 2009; Endicott, 2008; North Carolina Forestry BMP Manual; Montana Forestry BMP Manual). Most BMPs are based on relatively few guiding principles (Megahan and King, 2004; Olszewski and Jackson, 2006). These include:

- Use existing roads when practicable;
- Inventory road and stream conditions;
- Identify and avoid high-erosion hazard areas;
- Minimize the total land area disturbed;
- Minimize road crossings and other incursions into waterbodies;
- Engineer stable road surfaces, drainage features and stream crossings to reduce erosion;
- Separate bare ground from surface waters and minimize delivery of road-derived sediments to streams;
- Provide a forested buffer around streams;
- Design and install stream crossings to allow passage of fish, other aquatic biota, and large wood;
- Anticipate and mitigate erosion from precipitation events, including especially large ones;
- Regularly inspect all BMPs and erosion-prone areas, including during and/or immediately following precipitation and snowmelt events that may generate runoff; and
- Maintain forest roads and all BMPs.

EPA notes that BMPs currently play and historically have played a significant role in wet weather[4] and non-point source control programs. The scientific literature increasingly demonstrates the effectiveness of BMPs in preventing, minimizing, and mitigating discharges affecting water quality and aquatic habitats (Ice, 2004; Anderson and Lockaby, 2011; NCASI, 2012; Cristan *et al.,* 2016; Endicott (2008)). Although existing research has significantly improved the effectiveness of forest road BMPs, reducing water quality impacts from road construction and other practices, many discharges still occur (Anderson and Lockaby, 2011). Further research would help to optimize operation and maintenance and provide guidelines for adapting BMP implementation to site-specific needs.

Several commenters cited a report by Cristan *et al.* (2016) —"*Effectiveness of Forestry Best Management Practices in the United States: Literature Review*"— which summarized 81 BMP effectiveness studies: 30 studies of southern states, 20 studies of northern states, and 31 studies of western states.

The review concluded generally that:

- Forestry BMPs minimize water quality effects of forest operations when implemented as recommended by state forestry and water quality agencies.
- Forest roads, skid trails, and stream crossings warrant considerable attention because they have the greatest potential for erosion and sediment delivery.
- Many studies across the U.S. have shown BMPs to be effective and reduce sediment delivery to streams.

Several of the studies in the review assessed BMP performance and effectiveness in tandem and individually, including:

- Appelboom *et al.* (2002) sampled runoff from seven road practices in North Carolina and found that roads with continuous berm treatment had a 99% reduction in sediment loss compared to roads that did not have a continuous berm.
- Aust *et al.* (2011) evaluated four types of operational forest stream crossings at 23 crossings and approaches for total dissolved solids, pH, conductivity, temperature, and sediment concentration in the Piedmont region of Virginia during initial, installation, harvest, and closure stages. The authors found that bridge crossings had the least impact on water quality, that the installation and harvest phases had the greatest impact on water quality, and that BMPs should be followed during all phases.
- Wisconsin DNR (2006) published a BMP manual in 1995 and assessed the first ten years of their water quality program. The average BMP compliance rate was 83% and BMP effectiveness

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[4] 40 CFR 122.44(k).

was 99% when the appropriate BMPs were applied and maintained. When BMPs were not applied, water quality was affected 71% of the time.

- Pannill *et al.* (2000) evaluated Maryland BMPs in a paired watershed study and, based on TSS, stormflow, stream temperature, and macroinvertebrate data, found no significant water quality differences between pre-harvest and post-harvest, *i.e.*, proper BMPs will help protect water quality, biology, and habitat.
- Vowel (2001) conducted stream bioassessments using a stream condition index (SCI) for sites before and after silvicultural treatments incorporating Florida BMPs and found no significant differences in the SCI. The study concluded that Florida BMPs were effective in protecting water quality.

Cristan *et al.* (2016) also indicated that, in certain conditions, water quality effects can occur even when BMPs are used.

- Maryland DNR (2009) evaluated state BMPs from 2004–2005 on 75 forest harvested sites using a Maryland-specific BMP implementation checklist. Maryland found that 81% of those sites were in compliance with state BMPs standards. Maryland also found that BMPs were 77% effective in protecting water quality; however, they found that 19% of the sites evaluated delivered measurable sediment to waterways.
- Rice (1999) estimated the mean erosion rate from older logging roads (installed in the 1950s, maintained to standards of the 1980s) in the Redwood Creek watershed (northern California) to be 177 m^3 km$^{\text{minus;1}}$ from 1980 to 1997, mainly from the road cut banks, but noted that changes in forest practice rules (especially proper placement of culverts and sizing of culverts) reduced erosion on logging roads.
- Bilby *et al.* (1989) assessed road surface sediment production from five roads in two southwestern Washington watersheds including two heavily trafficked roads built in the 1950s and three haul roads built between 1968 and 1974 and found that sediment entered first and second order streams 34% of the time.
- Nolan *et al.* (2015) examined the effectiveness of BMPs at a number of stream crossings in Virginia. The study conducted an audit of BMP implementation rates, which it found can often function as surrogates for BMP effectiveness. In general, the study found that the majority of stream crossings were performing properly, but that performance varied. The study also cited Edwards and Williard (2010), which "found only three studies that provided BMP efficiencies with regard to sediment loading reductions and reported BMP efficiencies ranging from 53%–94%."
- The USFS evaluated its Pacific Southwest Region BMP program from 2008–2010, conducting 2,237 BMP inspections, and found that BMP implementation was 91% and effectiveness was 80%, with stream water quality impacts at 12% of the sites (USFS, 2013). BMPs for timber harvesting, fuels treatments, and vegetation management were effective; BMPs for roads, range management, recreation, and mining were not as effective, although effectiveness could be increased by imposing erosion control plans and wet weather standards.

EPA also considered other recently-published literature. Below are some of the major findings:

- The literature review *Assessing the Effectiveness of Contemporary Forestry Best Management Practices (BMPs): Focus on Roads* (NCASI, 2012) reviewed hundreds of studies and found that "implementing a suite of contemporary BMPs reduces sediment loads to streams by 80% or more relative to uncontrolled forestry operations." The document further concluded that "Specific BMPs for roads have been tested in controlled studies and proven effective by road inventories conducted by forestry agencies in several states. Those inventories show that road BMPs are being implemented at high rates and are effective in reducing risks to water quality; road drainage structures are being disconnected from streams; poor road/stream crossings are being identified and corrected; and landslides from forest roads are being reduced."
- The USFS (2012) National Best Management Practices for Water Quality Management on National Forest System Lands (Volume 1: National Core BMP Technical Guide), provides highly detailed guidance on silvicultural BMPs, including those for forest roads. BMP effectiveness ratings were 93% (Pacific Southwest Region) and 98% (Montana), with North Carolina effectiveness rates showing an increase from 73% to 93% between 1992 and 2010. Guidance to standardize BMP monitoring protocols is under development.
- Ice *et al.* (2010) estimated national BMP implementation rates at 89%.
- Sugden *et al.* (2012) found that BMP implementation rates in Montana have increased over time, corresponding with a significant drop in the number of observed water quality impacts.

Below are findings from national-scale studies:

- Cristan *et al.* (2016) concluded that BMPs implementation rates and quality are critical to BMP effectiveness for reduction of erosion and sediment yield. Important BMP practices for forest roads include proper drainage structures, surfacing, erosion control of cut and fill slopes, traffic control, and closure. Sediment control structures applied to stream crossing approaches can significantly reduce runoff and sediment delivery.
- Ice *et al.* (2010) concluded that the combination of effective BMPs and a high rate of BMP implementation helps protect the water quality and beneficial uses of streams, lakes, and wetlands in forested environments.

VI. Existing BMP-Based Programs and Other EPA Tools

A broad array of BMP-based programs—including state and federal programs and private third-party certification programs—has been established to address forest roads in every state with significant forestry operations in the country. The following sections outline the nation's current landscape of state, federal, and third-party BMP based programs designed to control discharges from forest roads, and discuss the role of existing EPA tools in addressing stormwater discharges from forest roads. As highlighted below, available information indicates that these programs are tailored to address regional and local differences, that implementation rates are generally high, and that meaningful improvements have been and continue to be made in these programs over time. EPA did not obtain significant data about tribal programs addressing discharges from forest roads, so does not report on tribal programs in this section. EPA will seek to learn more about efforts to address stormwater discharges from forest roads on tribal lands as part of its continuing efforts to gather best practices data going forward.

A. State BMP-Based Programs

Data EPA obtained during the comment period indicates that all states with significant forestry operations have developed BMP manuals and most states have established forest management programs tailored to state-specific conditions (*e.g.*, topography, climate, and industry activity) that address runoff from forest roads. The data also indicates that BMPs are being implemented at increasing rates across the nation. A team of researchers from Virginia Polytechnic Institute and State University (Virginia Tech), in consultation with the National Association of State Foresters (NASF), surveyed all 50 states in 2013 to identify silvicultural activities addressed by BMPs, characterize the approaches to BMP implementation adopted by each state, determine the extent to which states are implementing BMP effectiveness monitoring, and summarize BMP implementation rates (NASF, 2015). The survey showed that most states have established forestry BMPs designed to protect water quality. According to the survey, these programs are a mix of regulatory (11 states), quasi-regulatory (19 states), and non-regulatory (20 states) programs. Those states with regulatory programs generally have some form of forest practices law or silvicultural BMP legislation. In states with quasi-regulatory programs, state law specifies desired outcomes but does not require specific BMPs to achieve that outcome.[5]

Existing state programs vary because they are designed to address state and site-specific factors. Prior assessments of state forestry BMP programs have found similar, generally consistent information.[6] [7] The following number of states have established forest road specific BMPs (Table 1).

TABLE 1—STATES WITH FOREST ROAD BMP PROGRAMS BASED ON ENDICOTT (2008)

Category of forest road BMP	Number of states
Construction	44
Drainage	41
Location/Spacing	38
Maintenance	40
Road Closure	24
Stabilization/Soils/Slope	32
Stream Crossings	40
SMZs/Bank Stabilization/ Buffer Strips	36
Wet Weather Use	10
Winter Operations	10
Training/Technical Assistance	23
Implementation/Effectiveness Monitoring	32
Compliance/Enforcement	30

1. Existing State Programs Are Tailored To Address State and Site-Specific Factors

One of the primary mechanisms for addressing water quality impacts of forest roads is individual states' forest practices polices, which generally establish standards for the design, operation and maintenance of forest roads applicable to conditions in their state. State forest road programs vary to some degree in their structure, requirements, and administration. Differences are based on legal, and socioeconomic factors as well as variations in climate, soils, topography, and aquatic biota. State programs generally establish both guiding principles and specific management practices that must be applied and adapted to a broad range of settings and conditions. Site-specific flexibility is important because no single set of requirements will be effective across the country. As EPA stated in its November 10, 2015 notice, "[t]he diversity of the forest road networks, the different classes of roads, the different local physical conditions, and the broad range of road conditions and uses indicate the importance of site specific BMP selection and implementation to protect water quality" (80 FR 69656). For example, commenters correctly pointed out that Florida's forest road BMPs need not recommend or discuss full-bench road construction and end hauling techniques, as Oregon's rules do, because Florida does not have landslide-prone terrain, while Oregon has steep terrain with the potential for landslides, where such construction and end hauling techniques would be appropriate (EPA–HQ–OW–2015–0668–0089).

2. State Programs Show High Implementation Rates

Data from the 2013 NASF survey indicated that both forestry and forest road BMPs are implemented broadly. BMP implementation surveys in 32 states (*i.e.,* those with significant forest management activity) between 2005 and 2013 showed an average forestry BMP implementation rate of 91% (NASF, 2015). Nationally, the survey suggests that implementation rates for forest road BMPs averaged 91.5% and stream crossing BMPs averaged 86.7% (NASF, 2015). The 2012 Southern Region Report published by the Southern Group of State Foresters (SGSF) found forest road BMP implementation rates for 11 states[8] range from 78–99%, with an average of 88%. In the SGSF report, stream crossing BMP implementation rates ranged from 72–98% and averaged 89% (SGSF BMP Report, 2012).

The NASF survey also indicated that forest road BMP implementation rates do not vary significantly regardless of whether the state program is regulatory, quasi-regulatory, or non-regulatory. The NASF survey indicated that implementation of forest roads BMPs in 8 regulatory reporting states averages 93.9%, while the implementation rates in the 11 quasi-regulatory reporting states and 13 non-regulatory reporting states averages 90.6% and 90.5%, respectively (NASF, 2015).

Plus, BMP implementation rates have improved and continue to improve over time. For example, from 2008—2012, the implementation rates for all forestry BMPs (including forest road and stream crossing BMPs) trended upward in the SGSF report. This included forest road BMP implementation rates and stream crossings BMP implementation rates, which increased from 87 to 90%, and from 85 to 89%, respectively (SGSF BMP Report, 2012).

In addition to state forest road BMP programs, several efforts have emerged over the past 10 years to improve monitoring of BMP programs. Regional groups have undertaken efforts to promote consistent and comparable forestry BMP program monitoring data. The SGSF and the Northeastern Area Association of State Foresters (NAASF) have developed regional BMP monitoring protocols that states in those regions are using.

SGSF developed *Silviculture Best Management Practices Implementation Monitoring, A Framework for State Forestry Agencies* (2007) to improve and maximize the integrity of BMP implementation monitoring in southern states (SGSF Regional BMP Framework Protocol, 2007). The framework, which is implemented by 13 southern states, Puerto Rico, and the U.S. Virgin Islands, is designed to provide guidance for monitoring forestry BMP implementation that results in data that are statistically sound, objective, and promote analytical consistency among states. The framework addresses monitoring frequency, site selection, practices to be evaluated, the basis for practice evaluation and reporting, scoring methodology, risk assessment, and follow-up actions.

Similar to the SGSF BMP monitoring framework, the USFS Northeastern Area State and Private Forestry and the Northeastern Area Association of State Foresters—Water Resources Committee have developed the Forestry BMP Protocol Project. The BMP Protocol is a standard method for monitoring the use and effectiveness of BMPs commonly used in timber harvesting. The BMP Protocol, which is available to 20 states, serves three functions: (1) Data collection, (2) data analysis, and (3) report generation. It collects data using a branched question set designed to address those areas of the timber harvest with the greatest potential to impact water resources (including haul roads and water crossings). The protocol was developed to document the use and effectiveness of BMPs in protecting water resources during forest harvesting operations; document the degree of compliance with the CWA, as well as the Coastal Zone Management Act and various state laws and regulations; assess water resource protection based on the effectiveness of a collective set of BMPs; increase credibility through the measurement of results; respond to public concerns regarding the potential effects of timber harvesting based on measured evidence; and identify opportunities for improvement in water resource protection by identifying causes of BMP failure. Both a Desk Reference and Field Guide have been developed for the monitoring protocol (BMP Manual Desk Reference, 2007; BMP Field Guide, 2007).

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[5] Such programs can include states where BMPs are not mandatory but enforcement actions can be taken against polluters.

[6] See 80 FR 69657–69658 (Nov. 10, 2015). Characterizations of state forestry BMP programs differ in some ways because of the way reviewers categorize the programs, aspects of the programs they review, different interpretations of program elements, and the fact that state forestry BMP programs have evolved and continue to evolve over time.

[7] Endicott, 2008. See Section 4 and Tables 4–1 and 4–2.

[8] Alabama, Arkansas, Florida, Georgia, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia.

Other factors are also facilitating the increasing rate of BMP implementation. For example, third-party certification programs, as discussed in detail in section VI.C of this document, all require BMP implementation and third-party audits to verify that timber companies conform to state standards. Forest certification programs have made important contributions to improved BMP implementation through logger training, landowner outreach, and water quality requirements. Other examples are the logger training and certification programs established by states and third-party programs, such as the SFI Logger Training and Education (2015) program, to ensure loggers are educated about the use and maintenance of appropriate forest road BMPs. Training is particularly important given the site-specific customization BMPs require. The best way to ensure optimal BMP selection and installation is through localized knowledge of climate, soils, forestry operations, and other factors, in combination with state-specific BMPs. Some commenters noted that the Forest Resources Association reports having trained more than 150,000 logging professionals since the inception of the forest certification program (EPA–HQ–OW–2015–0668–0089). For fiscal year 2015, West Virginia noted that 1,454 loggers received certification to supervise logging operations and assure BMPs were applied (EPA–HQ–OW–2015–0668–0075). Also, as one commenter noted, effective outreach and training programs have served to foster a culture of high BMP implementation rates such that BMPs have largely been institutionalized in the forestry community.

3. State Programs Continue To Evolve and Improve

States frequently revise their forest roads management guidance/regulations. States with significant forestry operations have mechanisms in place to evaluate the effectiveness of forestry BMPs and use monitoring and research results to revise these practices when necessary (typically by government appointed forestry boards, forestry commissions, or a mix of agencies, councils, or departments). For example, California Department of Forestry and Fire Protection revised its Forest Practice Rules in 2015 to better manage drainage and erosion from logging roads (EPA–HQ–OW–2015–0668–0055); Wisconsin DNR-Division of Forestry revised its Forest Management Guidelines in 2011,[9] including updating forestry BMPs for water quality; and the Oregon Board of Forestry increased the riparian zone buffer width for fish-bearing streams in 2015 (Oregon Riparian Rule, 2015). States, federal agencies and various stakeholder groups continue to enhance BMP prescriptions and identify the site-specific factors that influence their effectiveness. For example, industry commenters identified 36 states that have revised their forest road BMPs within the last ten years (EPA–HQ–OW–2015–0668–0089), and according to a recent state survey conducted by the National Association of State Foresters, 31 states (62%) have updated their forest roads management guidance/regulations since 2006.[10] EPA's own analysis also indicates that many states have revised their programs, with some being revised as recently as 2016 (State Program Summary, 2016).

B. Federal BMP-Based Programs

At the federal level, the USFS and the BLM have established programs to manage stormwater discharges from forest roads on federal lands. These agencies manage large tracts of forested lands, including lands that are actively being used for road building, road maintenance, logging operations, public and recreational use or other activities, and generally demonstrate sound environmental stewardship in managing these lands.

1. Summary of U.S. Forest Service Programs

The 193 million acres (780,000 km^2) of public land that are managed as national forests and grasslands are collectively known as the National Forest System. These lands are located in 44 states, Puerto Rico, and the Virgin Islands and comprise about 9% of the total land area in the U.S. The USFS manages approximately 20% of the Nation's forested area and nearly 10% of the Nation's rangelands (USFS Strategic Plan FY: 2015–2020). The lands are organized into 154 National Forests and 20 National Grasslands. The mission of the National Forest System is to manage the national forests and grasslands to meet the Agency's sustainable multiple-use mandate.

The USFS uses several tools and strategies, such as the Legacy Roads and Trails program, Watershed Condition Framework, and the National Best Management Practices Program, in addition to local programs, to maintain and improve watershed health and manage discharges from forest roads.

The Legacy Roads and Trails program assists the USFS in identifying legacy roads in national forests and grasslands. USFS targets projects that will minimize the discharge of stormwater by decommissioning, maintaining, or upgrading various roads. From 2009–2015, the USFS decommissioned 5,504 miles of National Forest System Roads and an additional 6,714 miles of unauthorized roads; reconstructed 13,413 miles of roads; and maintained 57,333 miles of roads per year during that period.

The USFS Watershed Condition Framework helps the USFS to assess watershed health in national forests and grasslands, identify and implement protective measures, and conduct ongoing watershed monitoring. Watershed conditions are categorized into three discrete categories or classes that reflect the health of the watershed. One primary emphasis of the watershed assessment is indicators that directly or indirectly impact soil and hydrologic functions as well as riparian and aquatic ecosystems. Initial watershed condition framework assessments for all watersheds on USFS lands were completed in 2011.[11]

In 2012 the USFS also initiated and began to implement a National BMP program integrating water resource protection into landscape management activities. The National BMP program is designed to improve agency performance, accountability, consistency, and efficiency in protecting water quality. The program consists of National Core BMPs, standardized monitoring protocols to evaluate BMP implementation and effectiveness of the National Core BMPs, and a data management system to store and analyze the resulting monitoring data. National Core BMPs address 11 subject areas affecting water quality. One of those subject areas is road management activity, which includes BMPs for travel management planning and analysis, road location and design, road construction, and stream crossings (USFS, 2012). The National BMP based program enables the USFS to document compliance with the management of nonpoint source pollution at local, regional, and national scales as well as address the 2012 land management planning rule requirement for national BMPs at 36 CFR 219.8(a)(4).

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[9] *http://dnr.wi.gov/topic/forestmanagement/guidelines.html.*

[10] *http://www.stateforesters.org/action-issues-and-policy/state-forestry-BMPs-map-o-o.*

[11] *http://www.fs.fed.us/biology/watershed/condition_framework.html.*

The USFS monitors road management BMP implementation and its effectiveness at protecting water, aquatic, or riparian resources through nine evaluation categories and/or time periods, some of which include: Construction and reconstruction of USFS system roads and/or waterbody crossings; after construction or reconstruction has been completed; long-term management and maintenance of USFS system roads; decommissioned roads after decommissioning activities have been completed; and roads, parking areas, and snow storage areas during snow removal and storage activities.

The USFS has also developed a National Core BMP Technical Guide intended to improve USFS accountability and performance in managing water quality programs. Many of the core BMPs in the National Core BMP Technical Guide address water quality. The Technical Guide also provides administrative directives to allow for the use of state, tribal, and local requirements and information to develop site-specific BMPs where needed (USFS, 2012). The USFS is currently developing a second volume of the National Core BMP Technical Guide that will provide standardized protocols for monitoring BMP implementation and effectiveness across all USFS lands.

Further, USFS has developed a suite of tools to identify and prioritize road segments at risk of impacting water quality. These tools operate at scales of detail ranging from using corporate road databases and digital elevation data to using detailed GPS surveys. These tools apply in watershed sediment load reduction plans for waters listed as impaired under the CWA and in forest restoration projects under the Collaborative Forest Landscape Restoration Program in the states of Idaho, Montana, and California. For example, the Geomorphic Road Analysis and Inventory Package (GRAIP) tool includes methods to inventory roads and analyze the inventory for surface erosion, and risks for gullies, landslides, and stream crossing failures. This tool can be used in combination with other field observations to assess forest roads.

As an example of implementation of the USFS's BMP programs, the USFS evaluated its Pacific Southwest Region BMP program from 2008–2010 through 2,237 BMP inspections. It found that BMP implementation was 91% and effectiveness was 80%, with water quality affected at streams on 12% of sites. The USFS is continually improving and updating its programs and tools as accomplishments are monitored and verified. In 2013, the USFS completed an interim National BMP monitoring database for the National BMP program. The USFS expects to integrate this interim database into an enterprise data management system in the future which will extend reporting and analysis capabilities of the database.

In fiscal year 2014, 97 USFS administrative units completed a total of 600 BMP evaluations as part of implementing in the National BMP monitoring program. As discussed above, the USFS national core BMPs address 11 subject areas that potentially could affect water quality, including "road management activities." Nine monitoring protocols have been developed for the road management activity BMPs. At least 1 BMP evaluation was completed on 87% of the USFS administrative units; over 100 evaluations were conducted for road management activity BMPs. Of the 600 total evaluations, 94% included implementation assessments, 90% included effectiveness assessments, and 85% included both implementation and effectiveness assessments.

Overall, 61% of the BMP implementation evaluations were rated as "fully implemented" or "mostly implemented." In addition, 65% of the BMP effectiveness evaluations were rated as "effective" or "mostly effective." For sites where BMP implementation and effectiveness were both evaluated, 56% had composite ratings of "excellent" or "good." For road management activities, approximately 70% of the evaluations identified BMPs that were fully or mostly implemented. With regard to road management BMP effectiveness, approximately 50% of the completed evaluations were found to be effective or mostly effective. In the study the USFS acknowledges that these data show room for improvement in BMP implementation and effectiveness but observes that prior to development of the National BMP Program, it was impossible to report on BMP implementation and effectiveness on a national scale in a coherent, understandable, and useful way.

In December 2015, the USFS published the National Best Management Practices Monitoring Summary Report for the two-year BMP phase-in period of fiscal years 2013 and 2014 following the launch of the 2012 National Best Management Practices program. That report summarizes the national results of the two year phase-in period of national BMP monitoring. The report demonstrates the capabilities of a consistent nationwide monitoring program to document BMP performance (USFS, 2015). In addition, as part of the Watershed Condition Framework, the USFS is currently undertaking a five year re-assessment to assess changed conditions of USFS watersheds.

For example, USFS is using outputs from the GRAIP tool, mentioned previously, in combination with associated field observations to assess the effectiveness of road decommissioning in Idaho, Montana (Cissel *et al.,* 2014a), Oregon, Utah, and Washington. BMPs implemented as part of the decommissioning efforts resulted in a 79% reduction in fine sediment delivery to streams (Cissel *et al.,* 2014b).

The USFS implements best practices to control stormwater from forest roads on a program-wide scale in a number of ways, as well as ensuring that specific projects are implemented properly. Where a USFS road crew is in place, the agency performs maintenance and construction/reconstruction to the extent the law allows. BMPs are followed according to USFS policy, incorporating any national, regional, and local level BMPs. Crews work closely with local resource specialists to ensure work is being performed according to BMPs. When a project is awarded under a contract, clauses, provisions, mitigation measures, and BMPs are incorporated into the plans, specifications, and contract documents. For example, some contract provisions require the contractor to preserve, protect, and minimize the impacts from soil erosion to streams, lakes, and reservoirs.[12] A Contracting Officer or their certified designees monitor work performed by the contractor to ensure work compliance with the terms and conditions set forth in the contract.

The USFS is a recognized leader in establishing road crossing techniques that provide for aquatic organism passage, or the ability for fish and other aquatic life to move up or downstream under roads. In 2005, the USFS created the National Inventory and Assessment Procedure to evaluate the effectiveness of current and remediated fish passages (USFS, 2005). Over 1,600 miles of habitat were restored in fiscal years 2011–2013 by aquatic organism passage projects funded through the USFS Legacy Roads and Trails Restoration program among others (USFS, 2014).

2. Summary of Bureau of Land Management Programs

BLM manages approximately 246 million acres of public lands (BLM, 2015). Most BLM lands are concentrated in 11 western states with scattered tracts in the various eastern states. Of the 246 million acres, approximately 50 million acres are forest or woodlands where approximately 6–7 million acres are managed for sustainable timber harvests. These areas are generally mesic sites with annual average precipitation that usually exceeds 15 inches per year. Traditional timber harvesting on BLM property occurs primarily in northern California, Colorado, Idaho, Montana, Oregon, and Wyoming, with minimal harvest occurring in Alaska, Arizona, Nevada, New Mexico, and Utah. BLM uses several tools including land use plans, Memoranda of Understanding (''MOU'') with states and other federal agencies, timber sale contracts, and training to ensure protection of water resources.

Most BLM lands are managed pursuant to the Federal Land Policy and Management Act of 1976 (FLPMA), at 43. U.S.C. 1712, which requires public lands to be managed under the principles of multiple-use and sustained yield. BLM's land use planning regulations at 43 CFR part 1600 establish a land use planning system for BLM-managed public lands. Similar to the USFS, a full suite of activities are authorized and managed on BLM forests and woodlands, including timber harvesting, hazardous fuel reduction treatments, recreation, fish and wildlife conservation, oil and gas activities, and grazing. Authorized uses in forests and woodlands such as timber harvesting often include road construction and maintenance[13] which are broadly governed by policies, standards, and right-of-way agreements that ensure proper design and upkeep.[14]

One source of guidance for proper development of BLM land use plans is BLM's Land Use Planning Handbook. The Handbook provides broad agency direction for BLM to use BMPs to meet the standards and goals of the CWA and address various protection measures to mitigate impacts to human health concerns, ecosystem health, riparian areas, and overall watershed conditions, and to meet state and local water quality requirements (BLM, 2005).

BLM state offices enter into interagency MOUs with state and other federal agencies designed to ensure that they cooperatively meet state and federal BMPs and water quality rules and regulations related to point and nonpoint source water pollution from BLM managed lands.[15] These MOUs clarify such issues as jurisdictional and statutory authorities, monitoring responsibilities, implementing effective BMPs, prioritizing restoration activities, and developing strategies to meet water quality standards. The Idaho Nonpoint Source Management Plan provides one example of such an MOU (Idaho DEQ, 2015). In addition, several components of BLM state and national level manuals apply to ground-disturbing activities and provide for consistent implementation of BMPs.[16]

Finally, all BLM timber sales contracts contain standard contract requirements that expressly require that the purchaser must comply with all applicable state and federal laws and regulations pertaining to water quality. Often, they include special provisions deemed necessary (*e.g.,* restrictions on wet weather operations, conditions addressing Endangered Species Act requirements, soil and aquatic protection requirements, *etc.*).[17] Individual BLM offices consistently add special provisions to timber sales as well as other ground disturbing activity contracts to ensure effective BMP implementation. Appropriate BMPs are identified at the Resource Management Plan level, analyzed during site-specific NEPA review process, and implemented in various ways such as direct performance by BLM crews or through a timber sale contract.

BLM also provides training for their specialists in all aspects of resource management including engineering (to include roads and facilities), forest management, fish and wildlife management, and hydrology. Training curricula include: Review of existing and new state and federal regulations, manuals, handbooks, and policies including compliance with BMPs; preparing and administering contracts; review of interagency agreements or MOUs; review of updates on monitoring, evaluating, and reporting protocols and agency monitoring databases; review of Resource Management Plans and amendments; and conducting National Environmental Policy Act reviews.

BLM incorporates BMPs into land use plans that include management of forest roads. The recently released western Oregon Proposed Resource Management Plan/Final Environmental Impact Statement, Appendix J provides one example of such a plan (BLM RMPWO Vol. 3 Appendix J, 2016). The BMPs for the western Oregon Proposed Resource Management Plan address various anticipated resource management actions including: Road and landing maintenance and construction, timber harvest activities, silviculture activities, surface source water for drinking water, and recreation management. These BMPs were developed in coordination with Oregon Department of Environmental Quality to cooperatively meet state and federal water quality regulations. Additional BMPs could be required for a particular project depending on site-specific needs and subsequent implementation and effectiveness monitoring. BLM field offices review the land use plan BMPs and select and apply the appropriate and applicable BMPs for a particular project. Those BMPs are incorporated into on-the-ground operations like timber sales, road maintenance, road construction, and riparian restoration projects.

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[12] See BLM. (2011). Contract for the Sale of Timber and Other Wood Products Lump Sum Sale.

[13] Bureau of Land Management estimates that as of 2014 there were approximately 72,300 miles of roads on Bureau of Land Management lands (Public Land Statistics Table 6.2, pg. 246). Only a subset of these roads are located in forested environments that would have the potential to contribute to stormwater runoff (Bureau of Land Management Supplemental Response 3/29/16).

[14] *http://www.blm.gov/wo/st/en/prog/more/forests_and_woodland.html.*

[15] An example of an interagency MOU between Bureau of Land Management, other federal agencies and the Idaho Department of Environmental Quality, can be found at *http://www.deq.idaho.gov/media/1041346-nps_program_implementation_mou_2013.pdf.*

[16] Bureau of Land Management Manual 9113 (Roads), 9115 (Primitive Roads including BMPs from the *Surface Operating Standards and Guidelines for Oil and Gas Exploration and Development*), 7240 (Water Quality), Manual 5000 Forest Management (pertaining to timber sale contracts and specific contract provisions to apply to forest roads to address water quality protection).

[17] ''Bureau of Land Management Standard Timber Sale Contract Language,'' Bureau of Land Management Form 5450–004, Sections 26, 27, & 28.

Although the BLM does not have a national BMP monitoring database like the USFS, it works closely with a number of state and federal agencies to annually monitor, evaluate, and report BMP compliance and effectiveness. One example demonstrating the success of resource management plans to protect water quality is the Northwest Forest Plan (NWFP). Approximately 2.5 million acres of forested BLM land falls within the area covered by the NWFP and those acres have been managed consistent with the NWFP standards and guidelines. All of those standards and guidelines were incorporated into the 1995 western Oregon resource management plans.

The Aquatic Conservation Strategy is an important element of the NWFP, which incorporates into the resource management plans the implementation of a riparian reserve system (*e.g.,* buffers) along streams as well as reducing road densities. Since 1995, western Oregon BLM Districts have decommissioned or obliterated over 883 miles of roads.

As mentioned above, BLM has released a proposed resource management plan and a final environmental impact statement for western Oregon BLM Districts to revise the 1995 resource management plans. Under the proposed resource management plan, the riparian reserve system, along with a late successional forest reserve system, would increase from 57% following the 1995 resource management plan to 64% following new guidelines. BLM has worked closely with over 20 cooperating agencies including U.S. Fish and Wildlife Service, National Marine Fisheries Service, and EPA to continue a comprehensive and regional strategy to maintain and improve aquatic resources in alignment with the overarching ecosystem principles and intent of the Aquatic Conservation Strategy of the NWFP under the new RMP.

The recently released "*Northwest Forest Plan Interagency Regional Monitoring: 20 Year Report, Status and Trends of Watershed Condition*" report summarizes the results of the twenty year interagency effort to implement an array of water quality protective measures in the Aquatic Conservation Strategy to maintain watershed health in that region (Northwest Forest Plan, 2015). The NWFP Aquatic Conservation Strategy consists of four components: Riparian reserves, key watersheds, watershed analysis, and watershed restoration. Once watershed conditions were evaluated and resource needs were identified, multiple agencies, as well as public stakeholders, partnered to complete millions-of-dollars' worth of watershed restoration work include: Providing fish passages through culvert removals, replacements, or bridge construction; obliterating, closing, or relocating streamside roads; vegetating disturbed areas; reducing hazardous fuel loads; upgrading road surfaces to reduce sediment runoff; and removing dams. Implementation of these four components has resulted in improved watershed conditions in many watersheds.

The recently released monitoring report's objective was to evaluate whether the NWFP Aquatic Conservation Strategy is achieving the goal of maintaining and restoring the condition of watersheds throughout the region covered by the NWFP. The report evaluated two subject areas: Upslope riparian areas for all watersheds with at least 5% federal ownership, and in-channel stream data (*e.g.,* temperature, sediment, and macroinvertebrates). The report compares the effectiveness of management practices under the aquatic conservation strategy direction for two periods: 1993 and 2012 for upslope riparian assessment, and rotational sampling between 2002–2009 and 2010–2013 for in-channel stream assessment. These monitoring data were used to detect trends and evaluate stream and upslope riparian conditions for 1,974 watersheds in the Pacific Northwest.

The report signified that there has been a slight positive shift in upslope riparian condition. Sediment scores were generally very high, indicating a low risk of roads delivering sediment to streams. Sharp declines in assessment scores were mainly driven by large wildfires, and were offset by moderate, broad-scale improvements in vegetation, and focused improvements related to road decommissioning.

BLM also uses technical tools for evaluation, planning, and assessment of water quality. BLM is applying the USFS GRAIP tool, as well as others, in western Oregon watersheds to assess the effectiveness of road decommissioning and in sediment load reduction plans for waters listed as impaired under the CWA. These tools will also be used to prioritize the backlog of deferred maintenance needs that are later identified in the western Oregon Final Environmental Impact Statement, Chapter 3, Trails and Travel Management.

Outside of western Oregon, BLM is involved with various state, regional, and national water quality monitoring efforts to assess management effectiveness including indirect effectiveness of BMPs related to forest management and roads. For example, BLM cooperates with the Montana State Environmental Quality Council to monitor how forest practices are affecting watersheds in Montana. Montana conducts BMP field reviews on state, federal, and private industrial and non-industrial forest lands to monitor BMP implementation and effectiveness. Montana's 2014 BMP review concluded that 96% of BMP practices were effective on federal lands (Montana DNRC, 2014).

BLM has conducted a number of successful watershed restoration efforts to improve water quality on BLM lands. One example is the BLM Headwaters Forest Reserve Road Restoration Project in California. Since 2000, BLM has worked with the Pacific Coast Fish, Wildlife and Wetlands Restoration Association to decommission and restore 26 miles of old logging roads throughout headwaters. An additional 5 miles of decommissioning is planned for the next several years.[18]

3. Federal Programs Are Evolving and Improving

Both the USFS and BLM have improved their programs that address water quality and stormwater from forest roads over the last several years. As noted above, the USFS launched a new National BMP program in 2012 and is currently monitoring the program for results. In addition, the USFS has enhanced its Road Preconstruction Handbook on Design[19] as well as the Transportation Structures Handbook on Hydraulics and Watershed Protection[20] to include design considerations for the construction and reconstruction of forest roads which minimize road and drainage impacts to the watershed. USFS Technology and Development Centers have created a number of publications to assist designers when addressing road/water interactions.[21] BLM has taken extensive efforts to improve its protection and restoration efforts of watersheds by addressing key resource areas and improving resource management plans. Even with limited resources, federal programs are using new technology to target highest priority problems in watersheds to mitigate water quality impacts and monitor watershed health and project effectiveness. Improved resource management plans and technology will likely continue to evolve and lead to greater improvements.

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[18] *http://blm.gov/ca/st/en/prog/nlcs/Headwaters_ForestReserve/restoration.html.*

[19] See FSH 7709.56 Chapter 40 at *http://www.fs.fed.us/dirindexhome/dughtml/fsh_1.html.*

[20] See FSH 7709.56b Chapter 60 at *http://www.fs.fed.us/dirindexhome/dughtml/fsh_1.html.*

[21] *http://www.fs.fed.us/eng/pubs/.*

C. Third-Party Certification BMP-Based Programs

In addition to state and federal forest road BMP programs, participation in third party forest certification programs has been increasing rapidly in the U.S. Forest management certification arose to foster an improved stewardship of working forestlands. Programs such as certifications, which provide information and disclosure to consumers, can generate significant beneficial impacts on the environment while imposing fewer costs on industries and producers than direct regulatory programs.[22] Requirements to disclose information to citizens and consumers can lead to beneficial change without specific behavioral mandates. Certification provides a market incentive to encourage landowner commitment to sustainable forest management. It also offers a stamp of approval for forest management practices that meet standards considered to be environmentally appropriate, socially beneficial, and economically viable.

The three largest forestry certification programs in the U.S. are the Forest Stewardship Council (FSC), the Sustainable Forestry Initiative (SFI), and the American Tree Farm System (ATFS). These programs promote higher rates of BMP implementation by mandating compliance with applicable state and local laws and applicable BMPs, whether regulatory or voluntary. They promote training/education (including continuing education) and the use of trained loggers, promote monitoring of forestry BMP implementation, and include mechanisms for addressing instances where BMP nonconformance is observed. FSC requires expanded protection for waterbodies where it deems state programs or existing guidelines insufficient to protect water quality.

EPA received comments from state forestry agencies highlighting the large areas of state forested land under one of the third-party certifications identified above. For example, the Idaho Department of Lands notes that over 1.5 million acres of forest lands in Idaho are privately held or owned and managed by industries that maintain third-party certification through SFI, FSC or ATFS (EPA–HQ–OW–2015–0668–0072). Maine has almost 8 million acres of forest land which is third-party certified (EPA–HQ–OW–2015–0668–0058); and in Mississippi almost 470,000 acres of public forest land is certified through the ATFS and audited annually to ensure proper BMP implementation (EPA–HQ–OW–2015–0668–0081).

The discussion below provides a brief description of the three major programs in the U.S., focusing on how they promote management practices for mitigating water quality impacts resulting from stormwater discharges from forest roads.

1. Forest Stewardship Council (FSC)

FSC is an independent group with open membership that first convened in 1993 to improve forest practices internationally through a voluntary, market-based approach. FSC's program places an emphasis on whole-forest conservation, including protecting water resources from effects of stormwater discharges from forest roads. FSC is the only standard that prohibits the use of certain pesticides and herbicides in the timber industry and prohibits large clearcuts where they threaten the ecological integrity of the forest.

FSC's program includes a series of overarching principles and more specific performance criteria. An example forest management certification criterion is Forest Management Standard Criterion C6.5, which states, "[w]ritten guidelines shall be prepared and implemented to: control erosion; minimize forest damage during harvesting, road construction, and all other mechanical disturbances; and protect water resources." One "indicator" of this criterion provides that "[f]orest operations meet or exceed BMPs that address components of the Criterion where the operation takes place." Another provides,

> [t]he transportation system, including design and placement of permanent and temporary haul roads, skid trails, recreational trails, water crossings and landings, is designed, constructed, maintained, and/or reconstructed to reduce short and long-term environmental impacts, habitat fragmentation, soil and water disturbance and cumulative adverse effects, while allowing for customary uses and use rights. This includes: access to all roads and trails (temporary and permanent), including recreational trails, and off-road travel, is controlled, as possible, to minimize ecological impacts; road density is minimized; erosion is minimized; sediment discharge to streams is minimized; there is free upstream and downstream passage for aquatic organisms; impacts of transportation systems on wildlife habitat and migration corridors are minimized; area converted to roads, landings and skid trails is minimized; habitat fragmentation is minimized; unneeded roads are closed and rehabilitated.

Yet another indicator requires that, "[a] monitoring program is in place to assess the condition and environmental impacts of the forest-road system." Certifiers are independent of FSC itself and the companies they audit.

2. Sustainable Forestry Initiative (SFI)

SFI is an independent, nonprofit organization that is responsible for maintaining, overseeing, and improving the SFI certification program. Across the U.S. and Canada, more than 280 million acres are certified to the SFI Forest Management Standard and additional acres are influenced by SFI Fiber Sourcing. SFI administers standards that address forest sustainability broadly and water quality specifically. The SFI 2015–2019 Forest Management Standard applies to any participating organization in the U.S. or Canada that owns or has management authority for forestlands and consists of measures designed to protect water quality, biodiversity, wildlife habitat, species at risk, and forests with exceptional conservation value. The measures require developing a program for certification and compliance that include monitoring BMPs during all phases of forestry activities, mapping of water resources, and recordkeeping. For example, Objective 3 in the Standard addresses "Protection and Maintenance of Water Resources—To protect the water quality of rivers, streams, lakes, wetlands, and other water bodies through meeting or exceeding best management practices." Under Objective 3, Performance Measure 3.1 provides that "Program Participants shall meet or exceed all applicable federal, provincial, state and local water quality laws, and meet or exceed best management practices developed under Canadian or EPA-approved water quality programs." Performance Measure 3.2 further provides, "Program Participants shall implement water, wetland, and riparian protection measures based on soil type, terrain, vegetation, ecological function, harvesting system, state (BMPs), provincial guidelines and other applicable factors." Objective 11 addresses "Training and Education" and Performance Measure 11.1 provides that "Program Participants shall require appropriate training of personnel and contractors so that they are competent to fulfill their responsibilities under the SFI 2015–2019 Forest Management Standard."

SFI noted in its comments that 95% of the fiber delivered to SFI Program Participant mills is delivered by harvesting professionals who have been trained in sustainable forestry practices (EPA–HQ–OW–2015–0668–0099). Additional Forest Management

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[22] From Thaler, R., & Sustein, C. (2009). Nudge.

Standard Objectives address Forest Management Planning (Objective 1) and Legal and Regulatory Compliance (Objective 9).

3. American Tree Farm System (ATFS)

ATFS is a program of the American Forest Foundation, and has a forest certification standard that applies to small landowners in the U.S. In 2009, ATFS had certified more than 25 million acres of privately owned forestland managed by over 90,000 family forest landowners. To become certified, ATFS landowners must own at least 10 acres of forestland and implement a written forest management plan; and follow ATFS and AFF's 2015–2020 Standards of Sustainability for Forest Certification for Private Forestlands. Tree farms are inspected and certified to assure proper forest management that includes the conservation of soil, water and wildlife. Standard 4: Air, Water, and Soil Protection provides that "[f]orest-management practices maintain or enhance the environment and ecosystems, including air, water, soil, and site quality." Performance Measure 4.1 provides that each "[l]andowner shall meet or exceed practices prescribed by state forestry BMPs that are applicable to the property."

4. Third-Party Certification Programs Are Regularly Updated

All three certification programs described above continue to update standards on a regular basis. FSC has continually revised its Principles and Criteria since 1994, with the most recent revision in 2012. FSC also developed a U.S. Forest Management Standard in July 2010, which was updated in September 2012. SFI revises its standards every five years, and has most recently updated them in January, 2015. ATFS is required to review its standards every five years as part of its conditions for endorsement by the Programme for Endorsement of Forest Certification, an umbrella organization that works with national certification programs to promote sustainable forest management.[23] All programs include opportunities for public and other stakeholder input through public comment periods, webinars, and surveys.

D. Existing EPA Tools That Address Stormwater Discharges From Forest Roads

In addition to the state, federal, and third-party BMP-based programs described above, EPA administers other programs under the CWA that address forest road discharges. Stormwater point source discharges from forest roads have traditionally been treated similarly to nonpoint sources of pollution under the CWA. EPA has addressed these discharges under Sections 303, 305, and 319 of the CWA, and for the coastal areas, under Section 6217 of the Coastal Nonpoint Source Pollution Control Program under the Coastal Zone Act and Reauthorization Amendments (CZARA).[24]

1. Section 319 of the CWA

Under Section 319 of the CWA, EPA provides technical and financial support to states in their administration of programs that address pollution from nonpoint sources and activities that are not required to be regulated by NPDES permits. Many state nonpoint source management programs, which include components for the implementation of forestry-related BMPs, were initiated and continue to be supported, in part, through the use of Section 319 grant funds. According to EPA's 2011 National Evaluation of the Section 319 Program of the CWA, at least 15 state programs (AL, AR, CA, GA, KY, LA, MT, NC, OK, OR, SC, TX, VA, WV, WY) administer state-wide forestry nonpoint source management programs aimed at addressing problems associated with forest harvesting operations. At least ten of these states (AL, AR, GA, KY, LA, NC, OK, SC, VA, WV) rely on Section 319 grant funding through the relevant state forestry agency to support water pollution controls associated with forestry activities. In many of these states, the state nonpoint source management control agency has a formal relationship with the state forestry commission (or agency or department) to jointly implement the forestry program. EPA guidance provides that states are expected to revise and update their programs every 5 years as part of ensuring eligibility for continued funding. (Nonpoint Source Program and Grants Guidelines for States and Territories, 2013).

States have flexibility under the Section 319 program to address problems not addressed by the NPDES program. State Section 319 programs may encompass watershed or water quality-based approaches aimed at meeting water quality standards directly; iterative, technology-based approaches based on best management practices or measures, applied on either a categorical or site-specific basis; or a mix of these approaches. State forestry BMP-based programs apply these approaches using forestry BMP prescriptions and monitoring to address water quality impairments including forest road runoff, and EPA approves these programs as part of the Agency's review of state nonpoint source programs.

EPA has developed a Grants Reporting and Tracking System (GRTS) to track projects that receive Section 319 grant funding. It also enables EPA and the states to characterize the types of projects funded with the use of Section 319(h) grant funds. A sample GRTS query of projects shows that a number of Section 319(h) grants have been provided to address forest roads, such as road construction and maintenance projects, across the country. (Grants Reporting and Tracking System Forestry Data Pull, 2016). Section 319 funding remains available to address forest roads impacts in those states which have prioritized this as an issue in their nonpoint source management plans.

EPA has published various guidance documents to assist forest owners in protecting waters from forestry related runoff, and to help states to implement their Section 319 control program. For example, EPA published the *National Management Measures to Control Nonpoint Source Pollution from Forestry* (EPA, 2005) which includes BMPs for road construction, reconstruction, and management. In 2007, EPA also provided funding assistance to the Pennsylvania Department of Transportation to develop a manual which provides national guidance on effective and efficient practices to apply on dirt and gravel roads to reduce erosion, sediment, and dust pollution.[25]

2. Section 6217 of CZARA

Section 6217 of CZARA addresses enhancements to state Coastal Zone Management Act (CZMA) programs through development and implementation of management measures for nonpoint source pollution control to restore and protect coastal waters. This program, which is administered jointly by EPA and the National Oceanic and Atmospheric Administration (NOAA), directs states and territories with approved CZMA programs to provide for implementation of management measures for controlling runoff from activities within six categories of nonpoint source activities, including forestry. Each coastal state or territory administering a CZMA program (approved by NOAA) is required to describe its program to implement nonpoint source pollution controls, known as management measures, in conformity with a guidance published by EPA under CZARA Section 6217(g). The guidance describes ten management measures for forestry, including management measures for planning, road construction/reconstruction, and road management. As implemented under a state's CZMA program, CZARA requires enforceable policies and mechanisms, as well as monitoring and tracking of management measure implementation. NOAA and EPA are required to review and approve coastal nonpoint programs of state and territorial CZMA programs, and state authorities are responsible for implementing these programs. In all, EPA and NOAA have reviewed the programs submitted by 33 states and territories and, in many cases, approved such submissions with conditions. Over time, affected states and territories took action to address the program conditions incrementally. Since the federal agencies' initial approvals with conditions, all but 10 states have now met all of the outstanding conditions.[26]

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[23] *http://www.pefc.org/.*

[24] 16 U.S.C. 1455b.

[25] *https://www.epa.gov/polluted-runoff-nonpoint-source-pollution/environmentally-sensitive-maintenance-dirt-and-gravel.*

3. Sections 305(b) and 303(b) of the CWA

Under Section 305(b) of the CWA, states are required to assess the quality of their surface waters and report this information to EPA. In addition, every 2 years Section 303(d) requires states to identify on their Section 303(d) lists, which they submit to EPA for approval, those waters that are not attaining water quality standards, referred to as "impaired waters," and waters not expected to attain water quality standards by the next two-year listing cycle, referred to as "threatened waters." 33 U.S.C. 1313(d)(1)(A); 40 CFR 130.7(b). States must also establish a priority ranking for establishing total maximum daily loads (TMDLs) of pollutants for those waters. *Id.* TMDLs are "pollution budgets" that calculate how much of a given pollutant a waterbody can assimilate, including a margin of safety, without exceeding its applicable water quality standards. 33 U.S.C. 1313(d)(1)(C). TMDLs also allocate shares of the waterbody's assimilative capacity for that pollutant to all of its point and nonpoint sources. 40 CFR 130.2(i). Pollutant allocations may be assigned to individual sources or aggregated to sectors such as forest roads. Like Section 303(d) lists, states submit TMDLs to EPA for approval.

Impaired waters lists and TMDLs established for those impaired waters are "informational tools," *Pronsolino* v. *Nastri,* 291 F.3d 1123, 1129 (9th Cir. 2002), that help states evaluate the significance of pollutant sources like forest roads in contributing to water quality impairments in the U.S and guide implementation of measures to address those impairments. Nationally, pathogens, mercury, other metals, sediment, nutrients, and organic enrichment/oxygen depletion are identified as the leading causes of impairment of all assessed water bodies, based on state electronic data submissions from 2004 through 2010.

While TMDLs at their core are pollutant loading calculations and allocations, they also can provide a "comprehensive framework" for pollution reduction in a body of water that fails to meet state water quality standards. *Amer. Farm Bureau Fed'n* v. *EPA,* 792 F.3d 281, 287–288 (3rd Cir. 2015). While approving or establishing a TMDL, EPA requires "reasonable assurance" from the states that their TMDL implementation plans will meet their stated goals, *i.e.,* achieve the TMDL's allocations and implement the applicable water quality standards. *Id.* at 300. In support of EPA's recently revised TMDL for Lake Champlain, for example, Vermont detailed specific actions it would take to reduce the flow of sediment into Lake Champlain, including enhancing its forest roads forest management practices to reduce erosion (EPA Region 1, 2016).

EPA considered national TMDL data to determine whether forest roads have been identified as sources of water quality impairment and addressed in TMDL load allocations designed to help meet water quality standards.[27] For example, Endicott (2008) indicates that in California TMDLs were required for 10 river basins where silviculture was identified as a potential source. EPA reviewed three of these TMDLs (Upper Main Eel River and Tributaries TMDL, 2004; Mad River TMDL, 2007; Redwood Creek TMDL, 2011) and found that roads and road related landslides were the leading anthropogenic cause of sediment loading in these watersheds. While EPA is unable to develop national-level summary data to describe the degree of impairments from forest roads, EPA notes that these and other TMDLs serve as existing CWA planning tools that guide silviculture-related pollutant reduction activities on a watershed-specific basis. See also *Pronsolino* v. *Nastri* supra at 1129, where the Ninth Circuit upheld an EPA-established TMDL addressing sediment pollution to the Garcia River caused by roads, timber-harvesting, road surfaces, and road and skid trail crossings.

VII. Rationale for EPA's Determination Not To Establish New Regulatory Requirements for Forest Roads Discharges

As discussed above, many rigorous programs exist at every level of government as well as in the private sector to address stormwater discharges from forest roads in the United States. The programs are regularly updated to reflect new technology and research findings, are specifically tailored for the locations in which they are implemented, and have high implementation rates. While these programs have limitations and may vary in their effectiveness, EPA has concluded that providing support for further improvement to these programs will be more effective in further addressing discharges from forest roads than would the establishment of a new federal regulatory program under CWA Section 402(p)(6).

A number of practical considerations also militate against the establishment of a new federal regulatory program for forest roads. These include the site-specific nature of the environmental problem, the complex ownership arrangements of forest roads, and the limited financial resources and legal tools for addressing these roads, all discussed further below. A new program could require the expenditure of substantial resources while duplicating or displacing existing programs, with limited incremental environmental results. EPA has determined that the theoretical benefits of creating a "federal floor" do not outweigh its certain implementation problems, high costs, and potential duplication or displacement of longstanding and maturing federal, state, and private initiatives to address stormwater discharges from forest roads.

A primary difficulty in establishing a new, nationwide regulatory regime is the variability in water quality impacts from forest roads across the country. Many factors affect the extent to which BMPs are needed and those best suited to particular locations, including physical and meteorological factors (*e.g.,* climate, topography, soil type), which affect the nature of erosion and sedimentation; the intensity of timber operations; and localized scientific research and water quality data. A national regulation addressing such site-specific issues would likely be either too general or too complicated to be successful. The current multi-faceted, multi-layered landscape best supports the site-and region-specific nature of effective BMPs.

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[26] *https://coast.noaa.gov/czm/pollutioncontrol/.*

[27] Unfortunately, EPA's national-level TMDL data does not contain detailed information on specific impairment sources such as forest roads. See, for example, the state report "2012 Pennsylvania Integrated Water Quality Monitoring and Assessment Report," which identifies silviculture as responsible for 19 miles of impairments on state waters. Even with state-level data such as this report (which still does not make an explicit connection between forest roads and impairments), EPA found it exceedingly difficult to gather and assess this type of data.

The options laid out in Section 402(p)(6) of the CWA, the authority pursuant to which EPA could have designated stormwater discharges from forest roads for regulation, resemble the existing universe of forest roads control programs in the U.S. The types of regulatory actions that EPA could hypothetically take under Section 402(p)(6) are similar to the types of requirements and programs that states and other entities across the U.S. have already established, as described above. Section 402(p)(6) authorizes EPA to: "establish priorities, establish requirements for state stormwater management programs, and establish expeditious deadlines" which may include "performance standards, guidelines, guidance, and management practices and treatment requirements, as appropriate." 33 U.S.C. § 1342(p)(6). Many "state stormwater management programs" already exist and address discharges from forest roads in a manner specifically tailored to conditions in each state. *See Decker* v. *Nw. Envtl. Def. Ctr.*, 133 S. Ct 1326, 1338 (2013) ("Indeed, Congress has given express instructions to the EPA to work 'in consultation with State and local officials' to alleviate stormwater pollution by developing the precise kind of best management practices Oregon has established here. 33 U. S. C. § 1342(p)(6)"). In addition, states, agencies and organizations, including the USFS and EPA, have published "guidelines" and "guidance" discussing "management practices." Every state and state organization that submitted comments to inform EPA's determination strongly opposed additional federal regulations. EPA has decided to help states strengthen their programs rather than supplant them, consistent with the CWA's policy to "recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution" and to plan the "use . . . of land and water resources." 33 U.S.C. 1251(b).

Supporting rather than duplicating state programs is also consistent with the CWA's policy of fostering governmental efficiency: to "encourage the drastic minimization of paperwork and interagency decision procedures, and the best use of available manpower and funds, so as to prevent needless duplication and unnecessary delays at all levels of government." 33 U.S.C. 1251(f). An EPA program would add another layer of bureaucracy for both regulators and the private sector, sow confusion about program requirements and responsibilities, and lead to an inefficient use of already thin management resources, all for potentially limited environmental benefit.

While Section 402(p)(6) could otherwise generally allow for regulation through some sort of permitting, Congress has specifically foreclosed that option for discharges "resulting from the conduct of the following silviculture activities conducted in accordance with standard industry practice: nursery operations, site preparation, reforestation and subsequent cultural treatment, thinning, prescribed burning, pest and fire control, harvesting operations, surface drainage, or road construction and maintenance." 33 U.S.C. 1342(*l*). Congress has also precluded third-party citizen suits to enforce any non-permitting program established under Section 402(p)(6) or any other limitations applied to silviculture activities. In the absence of these implementation and enforcement mechanisms, it would be difficult to provide for effective federal implementation and compliance assurance for a new set of national forest road discharges.

Some commenters urged EPA to establish mandatory requirements pursuant to Section 402(p)(6), including prioritization of forest management areas, requiring road inventories, and monitoring for water quality standards. Many of these elements are part of state programs already. Requiring all forest landowners in the country to submit data to EPA about roads on their properties would necessitate a resource-intensive outreach operation. The large number of private family forest owners in the U.S. and Internet broadband limitations in rural areas, among many other factors, would make it difficult to ensure that forest road owners and operators are aware of and comply with such this requirements; legacy roads with no apparent owner would present even greater challenges. Additionally, as one commenter pointed out, many programs are targeted at certain impacted watersheds or aquatic species. An inventory of all forest roads, many of which do not cause water quality problems, does not necessarily provide information needed to address these particular impacts. Obtaining forest roads inventory information would likely be easier where large areas of forest are managed by a single entity, such as the USFS, but those entities are the ones most likely to already be engaging in inventory efforts (as described in section VI.B.1 of this document). Given these challenges, EPA does not believe that creating a new federal inventory of forest roads is a cost-effective use of EPA's limited resources.

Requiring water quality monitoring poses another distinct set of problems. Water quality monitoring is in-situ (ambient water) sampling for one or a selected set of environmental indicators. These metrics can be biological (*e.g.*, macroinvertebrates or fish community health), chemical (*e.g.*, pollutant concentrations), or physical (*e.g.*, geomorphology). This approach is not typically used to assess one or a few BMPs because in-situ water quality is influenced by multiple local and upstream factors/sources, and statistical distinctions between these factors and determining relative contributions may be impossible. Endicott (2008) reported findings "that the biotic and chemical 'noise' in larger streams renders the water quality effects of forestry activities using BMPs undetectable."

EPA recognizes that existing forest road BMP programs have limitations, including limited funding. Resource constraints are a primary difficulty facing both state and federal programs, limiting their abilities to implement and monitor BMPs. Yet a new set of requirements from EPA would not address the funding gap. Indeed, another federal program could divert resources from on-the-ground stream protection efforts to bureaucratic reshuffling. EPA has decided not to expend resources on creating, implementing, and enforcing a new national program that may not tangibly improve water quality.

VIII. Facilitating Continuous Improvement of Forest Road Programs

As discussed above, programs at the state, federal, and local levels, as well as within the private sector, have demonstrated positive momentum in strengthening efforts to address stormwater discharges from forest roads. EPA seeks to further facilitate continuing improvements in working to address water quality impacts from forest roads. Thus, rather than superimposing additional EPA-regulatory programs over existing programs, EPA plans to help strengthen these existing programs by forming an ongoing dialogue with all relevant stakeholders (including industry, environmental groups, academics, and government agencies at the federal, state, tribal, and local levels) on program improvements, technical and policy issues, research results, state of the art technologies, success stories, and solutions to problem areas. This forum could provide an opportunity for stakeholders to exchange information and expertise. EPA envisions that a major part of these discussions will focus on specific problems and solutions to forest roads, such as existing/legacy roads or stream crossings as well as particularly effective forest road programs and best practices. Working with stakeholders collaboratively, the forum could develop a national compendium of highly effective components of private or governmental forest roads programs to serve as a resource for states, tribes, federal agencies, local government, and industry. The compendium could serve as an indicator of expectations for development, implementation, and/or revisions of forest road programs by highlighting existing robust efforts and the latest developments of evolving strong programs.

IX. Response to Key Comments on Existing BMP-Based Programs

The discussion below responds to significant issues commenters raised with regard to the effectiveness of existing BMP-based programs.

Some commenters expressed concerns about the effectiveness of BMPs. In response, EPA makes an important distinction between the well documented ability of properly implemented BMPs to adequately control the discharge of pollutants, and situations where BMPs are improperly implemented or maintained (see multiple studies discussed in Part V). As these studies generally conclude, most BMPs are highly effective when appropriately designed and implemented; this includes choosing the right practice for particular situations and ensuring proper operation and maintenance. BMPs are ineffective or perform sub-optimally when not properly sited, installed, or maintained. These paradigms hold true for all water quality control technologies, not just BMPs, and underscore the importance of vigilant operation and maintenance rather than a conclusion that BMPs are not effective at protecting water quality. For example, Wisconsin DNR (2013) found that when BMPs were applied correctly no adverse impacts to water quality were found 99% of the time, and Montana DNRC (2014) reported that Montana's forestry BMPs were effective in protecting soil and water resources 98% of the time. In addition, as with most technologies, it is important to note that BMP science continues to evolve and improve.

One commenter mentioned a study of two watersheds in the U.S. Pacific Northwest region, which found that 44% of 80 sediment debris slides were associated with roads, even though roads comprised only 3.1% of the area. However, the authors of the study concluded that standard BMPs were the best approach to reducing erosion and sediment delivery rates. This is the approach that states and others are already pursuing in that region.

Another commenter pointed to low BMP efficiency data in Edwards and Williard (2010, as cited in Nolan *et al.*, 2015) but the cited article examined the efficiency of forest harvesting BMPs in reducing sediment, not BMPs related to forest roads in particular. EPA also recognizes that state BMP-based programs have limitations, including that they may not be fully implemented, that their effectiveness differs based on numerous variables, and the difficulty in measuring quantitative results.[28] A new federal regulatory program under CWA Section 402(p)(6), however, would not necessarily improve implementation rates, especially given the new limitations in CWA Section 402(*l*), which preclude the use of permits to implement any such program or of citizen suits to enforce any new federal requirements.

A few commenters discussed specific state forest road programs, such as Oregon's and Washington's. One commenter stated that Oregon's forest roads program is too flexible and is not adequately enforced. The commenter specifically identified the approval/rejection process for written plans as not being sufficiently stringent because there is no requirement to approve or deny a plan. With regard to Oregon (and other states), given the nature and scope of the concerns posed by forest road runoff, a reasonable degree of flexibility is valuable, as it allows for a tailored approach to addressing forest road discharges. *See Decker* v. *NEDC,* ("Oregon has invested substantial time and money in establishing these practices. In addition, the development, siting, maintenance, and regulation of roads—and in particular of state forest roads—are areas in which Oregon has considerable expertise").

Another commenter stated that, in addition to requiring BMPs, Washington State also requires water quality-based numeric criteria for turbidity and has rules for antidegradation, and that this should be required of all states. With regard to Washington State, EPA recognizes that states currently have various approaches to addressing sedimentation concerns (*e.g.,* numeric and narrative turbidity standards, dissolved oxygen standards, temperature standards, *etc.*) as part of their water quality standards programs. EPA agrees that applying numeric standards can be extremely effective in protecting water quality. However, states are well situated to understand the scope and nature of environmental concerns posed by forest road runoff in their states and apply state water program requirements to those concerns accordingly.

Some commenters, urged EPA to implement a national water quality-based monitoring program for forest roads. Requiring water quality monitoring for stormwater discharges from forest roads is infeasible for the reasons discussed in Section VII. Examining forest road BMP implementation on existing roads indicates whether existing programs are taking available and reasonable steps to address water quality concerns. EPA recognizes that most evaluations and determinations of BMP implementation are qualitative, but nonetheless, that information constitutes the best available information for EPA to make its decision. Extreme storms can pose challenges to the use and performance of BMPs, but BMPs can be tailored to some degree in areas subject to such events. A federal regulation would not alleviate risks posed by extreme storms because it would not be fair or reasonable to impose BMPs in all extreme storm events.[29]

One commenter stated that forest road BMP programs tend to focus on construction of new roads and fail to address older roads, often built before BMPs were in place (*i.e.,* they are either "grandfathered in" or subject to requirements only when brought back into use, reconstructed, or at risk of significant failure). The commenter observed that older roads can be significant sources of sediment since they may be poorly located and built with few if any features to control erosion (citing Endicott 2008, which includes some studies that identify legacy roads as sources but do not provide data regarding sediment discharged by legacy roads). EPA recognizes that legacy roads present a challenge and a potential source of sediment. Legacy roads are also the most challenging types of roads to address through regulation, however. Legacy roads are often no longer in use, so there may not be an ongoing silvicultural operation to fund BMPs. They may have non-forest uses, also complicating responsibility and liability assignment, or they may not be used for a period of time while timber is growing and then they may be placed back into use when it is ready for harvest. Legacy roads may also be so overgrown with vegetation that their presence is no longer detectable.

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[28] For example, Virginia has an implementation rate of 78% for forest road BMPs (SGSF BMP Report, 2012). In addition, the following states report lower than the national average of 86.7% for BMP implementation rates of stream crossing BMPs: Vermont, 68%; North Carolina, 72%, Ohio, 78%, Maryland, 67%, and Oregon, 71%. (NASF, 2015).

[29] NPDES Bypass and Upset provisions at 40 CFR Sections 122.41(m) and (n) providing relief in certain circumstances to NPDES dischargers.

Nonetheless, several state programs require older roads to be upgraded to current BMP standards if they are brought back into service. Endicott (2008) indicates that 24 states had forest road BMPs that address road closure. A more recent review indicates that 34 states have BMPs that address forest road retirement (State Program Summary, 2016). Comments indicate that California, Washington, and Oregon are among those states having programs addressing legacy road issues.

A few commenters stated that stream crossings for forest roads are especially vulnerable locations that can lead to significant erosion. One commenter stated that 5% of truck road stream crossings in the southern Piedmont region of Virginia were not meeting the relevant stream crossing BMPs (Nolan *et al.,* 2015) and that failure to meet BMPs in these areas will have a disproportionately negative impact on water quality as compared to upland BMP violations. Another layer of regulations from EPA, however, would not guarantee that the remaining 5% of stream crossings would incorporate appropriate BMPs. While stream crossings are indeed a high risk area for forest road runoff, a recent EPA analysis of state programs showed that 46 states (92%) have developed BMPs for stream crossings. (State Program Summary, 2016). Additionally, BMP guidance documents addressing road placement make clear that roads should avoid or minimize stream crossings and riparian areas. Thus, a BMP based approach reduces the incidence of road-stream crossings and, when deemed unavoidable, BMPs have been developed to install stream crossings while minimizing erosion.

A commenter also stated that some states do not consider the effects of diversion and natural disturbances when designing BMPs for stream crossings. These are important factors to consider. They are not, however, the only variables considered in a stream crossing design; stream flow and volume, soil type, volume and type of vehicle traffic, climate, and many other factors also play a role in determining the optimal design for a stream crossing. Effective stream crossing BMPs depend on site-specific conditions, reflecting the difficulty of setting one-size-fits-all federal requirements. In one study, researchers examined the effects of upgrading poorly designed stream crossings and concluded that the enhanced stream crossings produced little sediment and that improved stream crossings could significantly reduce sediment contributions from forest roads (Nolan *et al.,* 2015). One commenter spoke favorably of several BMPs developed by the USFS for use at stream crossings and recommended that EPA adopt them nationally. EPA encourages state programs to consider USFS stream crossing BMPs for their menus of BMPs.

EPA also received several comments regarding the compliance and monitoring aspects of state programs. One commenter stated that BMP effectiveness rates are overstated and suggested that the appropriate baseline for comparison should be forests in their natural conditions with no roads, whereas most studies compare forest roads with BMPs to forest roads with no BMPs. The commenter also asserted that, based on three studies, the actual efficiency of forest road BMPs is 53–94%. EPA notes in response that forest roads play a critical role in silviculture, recreation, fire suppression, and other uses. EPA does not expect forest roads to be absent from the landscape and therefore does not think that virgin forest must always necessarily serve as the baseline for measuring BMP effectiveness.

A commenter also pointed out that most BMP monitoring[30] is conducted during dry periods, when effectiveness at preventing stormwater runoff may be more difficult to discern. The commenter noted that variability in BMP performance monitoring can be as high as 50–100%, which would require frequent sampling to distinguish sediment derived from forest roads versus other sources. A number of BMP performance studies are conducted under wet weather conditions, including most of those cited in Section V of this document. However, BMP effectiveness also can be assessed to a large extent in dry weather, as evidence of soil movement is often visible for a significant time period after rainfall events. For example, gullying or landslides will be clearly visible while sediment deposition in low areas or waterbodies will also be visible.

Another commenter stated that standardizing BMP compliance assessments and reporting protocols is necessary. They add that most monitoring focuses on whether a BMP has been implemented, rather than monitoring water quality for compliance with water quality standards. The commenter cited data from Virginia that noted a 32% non-compliance rate for stream crossing BMPs. EPA recognizes that states have used a variety of monitoring and reporting mechanisms over time and that this can inhibit broader analyses about BMP compliance. However, as discussed in Section VI.A.2 of this document, two large groups of states have adopted regional standardized monitoring protocols to promote consistency in compliance assessment and reporting.

First, the SGSF has been implementing a broad monitoring program in 13 southeastern states for nearly a decade. Second, the joint effort between USFS and NAASF developed a similar standardized protocol for evaluating BMP implementation and effectiveness. These two protocols have spread a standardized monitoring process to a significant number of states with active forestry programs. Such standardization efforts are examples of the type of intra-state consistency that a federal EPA program could theoretically institute; their spread in the absence of EPA regulations provides an example in which a new EPA program would be duplicative.

Some commenters stated the lack of a national BMP program leads to inconsistent BMP application and insufficient water quality protections. EPA sees the range of designs in BMP programs as an appropriate response to the diversity of conditions these programs are intended to address. State or regional timber operations vary in intensity, as do the types of forest management programs states or other oversight agencies implement. BMPs used at a site will differ depending on the factors above, as well as others, such as localized scientific research that determines the most effective approaches to managing stormwater. Within different state frameworks, certain aspects of BMP programs are largely consistent. For example, state BMP categories typically encompass forest road location/design/construction; road maintenance; stream crossings; stream management zones/bank stabilization/buffer strips; and many states address forest road retirement and wet weather/winter use.

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[30] BMP monitoring refers in this case to assessment of BMP performance effectiveness, which includes verifying that the structure/measures are in place and functioning. BMP monitoring is different from water quality monitoring, which involves monitoring a waterbody for particular environmental indicators.

Many states are taking the lead in enhancing their programs to encompass newly developed methods to reduce water quality impacts from forest roads. For example, CA's "Road Rules, 2013", which was first implemented in January 2015, requires that all forest roads used as part of an approved plan be hydrologically disconnected from waters (EPA–HQ–OW–2015–0668–0055). In the Southern region, the Southern Group of State Foresters Silviculture Best Management Practices Implementation Monitoring framework requires all southern states to include in their implementation monitoring reports counts of water quality risks. Finally, while "traditionally a problem area within all states, compliance with stream crossing BMPs continues to improve as a result of increased education of landowners and managers as well as increased acreage of certified forestland in the region (Schilling *et al.*, 2009)." [Ice *et al.*, 2010.]

One commenter stated, "Congress has failed to adequately invest in the National Forest System roads budget. Annual spending has declined from over $236 million to less than $159 million in the last six fiscal years, when adjusted for inflation." This has helped to contribute to the development of a more than $5 billion deferred maintenance backlog on the National Forest System. This commenter also suggested that, "[r]egulating stormwater discharges from USFS roads will do nothing to address either the forest health crisis or the disinvestment in maintaining the existing Forest Road system" (*Id.).* EPA acknowledges that both the USFS and BLM face resource constraints, often must address higher priority issues such as fire suppression to protect lives, and confront other challenges that limit the ability to fully address all issues arising from forest road activity when it comes to maintaining their transportation networks. Another layer of EPA regulations, in addition to existing federal programs addressing water resources protection and restoration, would not address these resources constraints and would likely do little to enhance water quality.

In conclusion, none of these comments alters EPA's determination not to establish a new regulatory program for discharges from forest roads under CWA Section 402(p)(6). While EPA recognizes that discharges from forest roads have significant impacts on water quality in many parts of the country, the Agency has concluded that the most effective way to make further progress in addressing these issues is to support existing state, tribal, federal, and third-party programs. Given the diversity of forest roads programs in this country, some programs will necessarily be more rigorous than others. EPA has considered this variability, but concluded that any consistency that a national regulation could theoretically achieve is far outweighed by the challenges of its implementation.

X. References

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Dated: June 27, 2016.

Joel Beauvais,

Deputy Assistant Administrator, Office of Water.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC–2015–0063, NIOSH–287]

RIN 0920–AA61

World Trade Center Health Program; Addition of New-Onset Chronic Obstructive Pulmonary Disease and WTC-Related Acute Traumatic Injury to the List of WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: The World Trade Center (WTC) Health Program conducted a review of published, peer-reviewed epidemiologic studies regarding potential evidence of chronic obstructive pulmonary disease (COPD) and acute traumatic injury among individuals who were responders to or survivors of the September 11, 2001, terrorist attacks. The Administrator of the WTC Health Program (Administrator) found that these studies provide substantial evidence to support a causal association between each of these health conditions and 9/11 exposures. As a result, the Administrator is publishing a final rule to add both new-onset COPD and WTC-related acute traumatic injury to the List of WTC-Related Health Conditions eligible for treatment coverage in the WTC Health Program.

DATES: This rule is effective on August 4, 2016.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Ave, MS: C–46, Cincinnati, OH 45226; telephone (855)818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

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I. Executive Summary

A. Purpose of Regulatory Action

This rulemaking is being conducted in order to add new-onset COPD and WTC-related acute traumatic injury [1] to the List of WTC-Related Health Conditions (List). Following the receipt of letters from the directors of the WTC Health Program Clinical Centers of Excellence (CCEs) and Data Centers to the WTC Health Program supporting coverage of all cases of COPD (including new-onset COPD) and significant traumatic injuries within the Program,[2] the Administrator decided to conduct literature reviews regarding COPD and acute traumatic injuries among 9/11 responders and survivors. Based on the findings of those reviews, he determined that the evidence for causal associations between 9/11 exposures and new-onset COPD and acute traumatic injury, respectively, provides sufficient bases for the addition of both health conditions to the List. The Administrator published a proposed rule to add new-onset COPD and acute traumatic injury to the List on September 11, 2015,[3] and finalizes the rule in this action.

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[1] The term "WTC-related" was not included in the proposed definition of acute traumatic injury in the notice of proposed rulemaking, 80 FR 54746 (Sept. 11, 2015), but has been added in the final rule to clarify specific usage in the WTC Health Program and better parallel "WTC-related musculoskeletal disorder" on the List. The Administrator finds that revising the term results in no substantive change from the proposed rule. *See* discussion *infra* Section VIII.

[2] Michael Crane, Roberto Lucchini, Jacqueline Moline, *et al., Letter from CCE and Data Center Directors to Dori Reissman and John Halpin, WTC Health Program Regarding "Musculoskeletal Conditions,"* May 11, 2014; and Michael Crane, Roberto Lucchini, Jacqueline Moline, *et al., Letter from CCE and Data Center Directors to Dori Reissman and John Halpin, WTC Health Program Regarding "Rationale for the Continued Certification of COPD as a World Trade Center Related and Covered Condition,"* Apr. 22, 2014. These letters are included in the docket for this rulemaking.

B. Summary of Major Provisions

This final rule adds new-onset COPD and WTC-related acute traumatic injury to the List of WTC-Related Health Conditions in 42 CFR 88.1. As of the effective date of this rule, these conditions will be eligible for treatment by the WTC Health Program.

C. Costs and Benefits

The addition of new-onset COPD and WTC-related acute traumatic injury to the List of WTC-Related Health Conditions through this rulemaking is estimated to cost the WTC Health Program from $4,602,162 to $5,666,713 annually, between 2016 and 2019. All of the costs to the WTC Health Program are transfers. Benefits to current and future WTC Health Program members may include improved access to care and better treatment outcomes than in the absence of Program coverage.

II. Public Participation

On September 11, 2015, the Administrator published a notice of proposed rulemaking (NPRM) to propose the addition of new-onset COPD and acute traumatic injury to the List in 42 CFR 88.1.[4] The Administrator asked peer reviewers to evaluate the scientific literature review and Administrator's determination and invited interested members of the public or organizations to participate in the rulemaking by submitting written views, opinions, recommendations, and/or data. This final rule describes feedback received from both peer reviewers and public commenters.

A total of six peer reviewers were charged with reviewing the Administrator's evaluation of the evidence for adding the two conditions to the List. Three pulmonary disease experts reviewed the evidence for the addition of new-onset COPD and three injury experts reviewed the evidence for the addition of acute traumatic injury. Specifically, the peer reviewers were asked to answer the following questions:

1. Are you aware of any other studies which should be considered? If so, please identify them.
2. Have the requirements of the *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*[5] appropriately been fulfilled? If not, please explain which elements are missing or deficient.
3. Is the interpretation of the available data appropriate, and does it support the conclusion? If not, please explain why.

Public comments were invited on any topic related to the proposed rule, and specifically on the following questions:

1. Is September 11, 2003 an appropriate deadline by which an individual must have received initial medical treatment for an acute traumatic injury?
2. Is there evidence of acute traumatic injuries that occurred as a result of the September 11, 2001, terrorist attacks that would not be covered by the proposed definition? What are the types of long-term consequences or medically associated health conditions that result from the treatment or progression of acute traumatic injuries like those sustained on or after September 11, 2001?
3. Are data available on the chronic care needs of individuals who suffered acute traumatic injuries during the September 11, 2001, terrorist attacks, and its aftermath that the Administrator can use to estimate the number of current and future WTC Health Program members who may seek certification of WTC-related acute traumatic injury as well as treatment costs?
4. Are data available on the prevalence and cost estimates for new-onset COPD?

The Administrator received 16 submissions to the rulemaking docket from the public, including the following individuals and organizations: 10 unaffiliated commenters; one individual who is a responder or survivor; two self-identified responders; sister non-profit organizations dedicated to preventing and curing alpha-1 antitrypsin deficiency and COPD; a labor union; and the WTC Health Program Survivors and Responders Steering Committees.

The peer reviews and public comments are found in the docket for this rulemaking. Summaries of all peer reviews and public comments, as well as the Administrator's responses, are found below.

III. Background

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act), Public Law 111–347, as amended by Public Law 114–113, added Title XXXIII to the Public Health Service Act (PHS Act),[6] establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this document mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee. Section 3312(a)(6) of the PHS Act requires the Administrator to conduct rulemaking to propose the addition of a health condition to the List codified in 42 CFR 88.1.

B. Evidence Supporting the Addition of New-Onset COPD and WTC-Related Acute Traumatic Injury to the List of WTC-Related Health Conditions

Consideration of an addition to the List may be initiated at the Administrator's discretion[7] or following receipt of a petition by an interested party.[8] Under 42 CFR 88.17, the Administrator has established a process by which health conditions may be considered for addition to the List of WTC-Related Health Conditions in § 88.1. Pursuant to section 3312(a)(6)(D) of the PHS Act, whenever the Administrator determines that a condition should be proposed for addition to the List, he is required to publish an NPRM and allow interested parties to comment on the proposed rule.

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[3] 80 FR 54746.

[4] *Id.*

[5] John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* revised Oct. 21, 2014, *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.*

[6] Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the Zadroga Act found in Titles II and III of Pub. L. 111–347 do not pertain to the WTC Health Program and are codified elsewhere.

[7] PHS Act, sec. 3312(a)(6)(A); 42 CFR 88.17(b).

[8] PHS Act, sec. 3312(a)(6)(B); 42 CFR 88.17(a).

The Administrator also follows the WTC Health Program's policy and procedures for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions, published online in the Policies and Procedures section of the WTC Health Program Web site.[9] The Administrator amended the policy since it was used to conduct the analysis of COPD and acute traumatic injury studies for the NPRM;[10] changes to the policy are not substantive and are intended to clarify terminology and specific procedures. The policy's descriptions of what studies will be evaluated in the literature evidence review and analyzed in the scientific and medical assessment have been revised to clarify the types of studies considered peer-reviewed, published, epidemiologic studies.[11] The Administrator has also revised an existing footnote regarding distinct criteria for assessing certain conditions with immediate and observable cause and effect.[12] These criteria were already included in the assessment conducted for the analysis of acute traumatic injury studies published in the NPRM.[13] In accordance with the policy, the Administrator directed the WTC Health Program Associate Director for Science (ADS) to conduct a review of the scientific literature to determine if the available scientific information on COPD and acute traumatic injury, respectively, had the potential to provide a basis for a decision on whether to add the conditions to the List. The literature review included published, peer-reviewed epidemiologic studies, including direct observational studies,[14] about each health condition among 9/11-exposed populations. The studies were reviewed for their relevance, quantity, and quality to determine whether they had the potential to provide a sufficient basis for the Administrator's decision to propose adding each health condition to the List.

After finding that the available evidence had the potential to provide bases for the decisions, the ADS further assessed the scientific and medical evidence to determine whether causal associations between 9/11 exposures and new-onset COPD and acute traumatic injury, respectively, were supported. A health condition may be added to the List if published, peer-reviewed epidemiologic studies provide substantial support [15] for a causal association between 9/11 exposures and the health condition in 9/11-exposed populations.

In this case, the Administrator finds there is substantial evidence in published, peer-reviewed epidemiologic studies that 9/11 exposures produced chronic airway inflammation manifested by persistent lower respiratory symptomatology and decline in pulmonary function, which progressed to new-onset COPD in a proportion of exposed subjects in the period since exposure, independently from any cigarette smoking among the cohort. This evidence provides substantial support for a causal association between 9/11 exposures and new-onset COPD.

The Administrator also finds that evidence in the published, peer-reviewed epidemiologic studies evaluated by the ADS provides substantial support for a causal association between 9/11 exposures and acute traumatic injuries among responders and survivors to the September 11, 2001, terrorist attacks.

The reviews of evidence and Administrator's determinations concerning the addition of new-onset COPD [16] and WTC-related acute traumatic injury [17] are found, in full, in the NPRM.

IV. Effects of Rulemaking on Federal Agencies

Title II of the Zadroga Act reactivated the September 11th Victim Compensation Fund (VCF). Administered by the U.S. Department of Justice (DOJ), the VCF provides compensation to any individual or representative of a deceased individual who was physically injured or killed as a result of the September 11, 2001, terrorist attacks or during the debris removal. Eligibility criteria for compensation by the VCF include a list of presumptively covered health conditions, which are physical injuries determined to be WTC-related health conditions by the WTC Health Program. Pursuant to DOJ regulations, the VCF Special Master is required to update the list of presumptively covered conditions when the List of WTC-Related Health Conditions in 42 CFR 88.1 is updated.[18]

V. Summary of Peer Reviews and Public Comments—New-Onset COPD

As discussed above in the Public Participation section, the Administrator solicited reviews of the NPRM by three experts in the field of pulmonary disease who provided peer review of the evidence supporting the addition of new-onset COPD. In addition to the peer reviews, the Administrator received submissions from public commenters. The COPD-related peer reviews and public comments are summarized below, and each is followed by a response from the Administrator.

A. Peer Review

First, peer reviewers were asked whether they were aware of any other studies which should have been considered in the NPRM, with regard to new-onset COPD. Second, the peer reviewers were asked whether the requirements of the *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* described above, had been fulfilled. Third, the peer reviewers were asked whether the Administrator's interpretation of the evidence for new-onset COPD was appropriate and whether it supported the decision to propose adding new-onset COPD to the List.

Identification of Other Studies To Support the Administrator's Determination

One new-onset COPD peer reviewer indicated that no additional articles concerning 9/11 exposures and new-onset COPD were identified. Two reviewers suggested additional studies that the Administrator should have considered.

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[9] John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* revised May 11, 2016, *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf.*

[10] An October 2014 version of the policy was used to conduct the review in the September 2015 NPRM. *See* John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* revised Oct. 21, 2014, *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.*

[11] The clarification of the description of the studies was made in response to peer review comments on the WTC-related acute traumatic injury analysis. *See* discussion of these comments *infra* Section VI.A.

[12] The footnote to the policy explains that injury studies are assessed for relevance, quantity, quality, known causation, and onsite occurrence and that information in the studies about injuries recorded in contemporaneous medical records and studies, combined with known hazards and known connections between those hazards and injury, may be useful to the Administrator's evaluation of any support for a causal association between those exposures and the injury. *See* footnote 12, John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* revised May 11, 2016, *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf.*

[13] 80 FR 54746, 54754.

[14] *See* discussion of these terms *infra* Section IV.A.

[15] The substantial evidence standard is met when the Program assesses all of the available, relevant information and determines with high confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

[16] *See* 80 FR 54746 at 54748.

[17] *Id.* at 54752–54754.

[18] 28 CFR 104.21(b).

One reviewer suggested three additional studies for the Administrator's consideration, two of which referenced 9/11 exposures among WTC responders with lower respiratory symptoms. The first study, Mauer *et al.*,[19] did not include spirometry, and the second study, Niles *et al.*,[20] did not specifically address the occurrence of COPD among the 9/11-exposed population but examined the extent to which early post-disaster symptoms and diagnoses accurately anticipate future healthcare needs. The third study, Lange *et al.*,[21] was not an epidemiologic study of 9/11-exposed populations, and thus was not further considered. As stated in the NPRM preamble, only epidemiologic studies that reported compatible new-onset, "post-9/11 lower respiratory symptomatology and objective measurements of airways obstruction, such as pre- and post-9/11 spirometry with bronchodilator administrator or IOS [impulse oscillometry] were found to exhibit potential support"[22] for a recommendation to add the health condition to the List and selected for further quality review. Since the Mauer and Niles studies did not meet this standard, they were not further reviewed.

The other reviewer suggested a review of the literature on non-smoking inhalational exposures, which are responsible for 15 percent of COPD cases, and noted that COPD can present years after relevant exposures. The Administrator agrees that COPD attributed to occupational and environmental exposures may present several years after cessation of exposures; however, the matter of maximum time intervals for the diagnosis of new-onset COPD is outside the scope of this rulemaking and will be addressed through Program policy and procedures.

One general comment recommended that the full search string be included in future assessments so that reviewers can replicate the literature search. The Administrator agrees; future assessments will include full search strings so that reviewers may replicate the ADS's literature review.[23]

Administrator's Compliance With Established Policy and Procedures To Add Non-Cancer Health Conditions to the List of WTC-Related Health Conditions

All three of the new-onset COPD peer reviewers agreed that the requirements of the policy had been fulfilled.

Administrator's Interpretation of Evidence for the Addition of New-Onset COPD

All three new-onset COPD reviewers found that the interpretation of the available literature was appropriate and supported the Administrator's conclusion. One reviewer identified challenges with establishing an operational definition of COPD and how the definition would be applied to WTC Health Program members. The reviewer asked whether an individual with potentially relevant symptoms (such as lower respiratory symptoms or symptoms of chronic bronchitis) and normal spirometry has COPD. The commenter noted that "obstructive chronic bronchitis," included in the description of COPD in the NPRM preamble, does not appear in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommendations, and its inclusion in the NPRM preamble implies that the WTC Health Program member would not be considered to have COPD if diagnosed with chronic bronchitis in the absence of demonstrated airflow obstruction. The reviewer also asked whether impulse oscillometry alone can support a COPD diagnosis, and pointed out that GOLD does not include impulse oscillometry as a diagnostic test for COPD. Finally, the reviewer asked whether the WTC Health Program will require identification of emphysema, included under the COPD category, by computerized tomography (CT) scan imaging even in the absence of demonstrated spirometric airflow obstruction.

The reviewer accurately notes the difficulties in choosing a single definition of COPD for the purpose of this rulemaking. As discussed in the NPRM, COPD is an umbrella term and encompasses a variety of pulmonary conditions; various definitions exist, making the interpretation of evidence for adding new-onset COPD to the List a challenge. The GOLD definition of COPD, which requires spirometric evidence of airflow limitation, was used to provide an objective parameter to evaluate the occurrence of COPD among the 9/11-exposed populations identified in the surveillance literature reviewed by the ADS. Chronic obstructive bronchitis is a subtype of chronic bronchitis associated with airflow limitation, as recognized by the National Heart, Lung, and Blood Institute.[24] Relying on the Merck Manual, the NPRM preamble utilized a definition of "obstructive chronic bronchitis" that emphasizes the need for spirometric evidence of airflow obstruction.

Diagnosis of COPD requires confirmation, using spirometry, of airflow limitation that is not fully reversible, as well as a history of potentially causative exposure among symptomatic individuals. In some circumstances, in addition to spirometry, impulse oscillometry may be presented to support the COPD diagnosis by detecting subtle changes in a patient's airways function earlier than with conventional spirometry.[25]

The WTC Health Program will provide specific instruction to physicians regarding diagnostic standards for new-onset COPD. Certification of cases of new-onset COPD in individual WTC Health Program members will be decided by the Program on a case-by-case basis, in accordance with section 3312(b)(2)(B) of the PHS Act and 42 CFR 88.13.

B. Public Comment

Support for New-Onset COPD

Many commenters expressed support for the addition of new-onset COPD to the List. One commenter found that the Administrator presented quality evidence that establishes a causal association between 9/11 exposures and new-onset COPD. Although some submissions only addressed the addition of acute traumatic injury, no commenters opposed the addition of new-onset COPD.

Additional Studies To Support the Addition of New-Onset COPD to the List

One commenter suggested the consideration of a 2010 study by

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[19] Matthew Mauer, Karen Cummings, Rebecca Hoen, *Long-Term Respiratory Symptoms in World Trade Center Responders,* Occup Med (Lond) 2010;60(2):145–51.

[20] Justin Niles, Mayris Webber, Hillel Cohen, *et al., The Respiratory Pyramid: From Symptoms to Disease in World Trade Center Exposed Firefighters,* Am J Ind Med 2013;56(8):870–80.

[21] Peter Lange, Bartolome Celli, Alvar Agustí, *et al., Lung-Function Trajectories Leading to Chronic Obstructive Pulmonary Disease,* N Engl J Med 2015;373:111–122.

[22] 80 FR 54746 at 54749.

[23] In the case of COPD, the full search string consisted of the following: ("chronic obstructive pulmonary disease" OR "chronic bronchitis" OR "pulmonary emphysema" OR "pulmonary function decline" OR "respiratory insufficiency" OR "airways obstruction" OR "airflow limitation") AND ("September 11 Terrorist Attacks" OR "World Trade Center" OR WTC OR "September 11" OR 9/11).

[24] *See* NIH, National Heart, Lung, and Blood Institute, *Executive Summary, http://www.nhlbi.nih.gov/research/reports/2011-bronchitis.*

[25] Christopher Cooper, *Assessment of Pulmonary Function in COPD,* Semin Respir Crit Care Med 2005;26(2):246–52.

Banauch *et al.*[26] to support the addition of COPD to the List. Another commenter offered a list of additional articles that should have been reviewed.

The Banauch study was reviewed and found to be relevant; however, it was not selected to undergo further evidence review due to its small number of study participants (n = 90). The papers cited by the second commenter were reviewed during the literature review process; however, only epidemiologic studies that reported compatible post-9/11 lower respiratory symptomatology and objective measurements of airways obstruction, such as pre- and post-9/11 spirometry with bronchodilator administration or impulse oscillometry were found to exhibit potential for a recommendation and selected for review. Two of the references offered by the commenter, Aldrich *et al.* and Weakley *et al.*, were included in the ADS's review published in the NPRM.

VI. Summary of Peer Reviews and Public Comments—WTC-Related Acute Traumatic Injury

As discussed above in the Public Participation section, the Administrator solicited reviews of the NPRM by three injury experts who provided peer review of the evidence supporting the addition of acute traumatic injury. In addition to the peer reviews, the Administrator received submissions from public commenters. All of the acute traumatic injury-related peer reviews and public comments are summarized below, and each is followed by a response from the Administrator.

A. Peer Review

First, with regard to acute traumatic injury, peer reviewers were asked whether they were aware of any other studies which should have been considered in the NPRM. Second, the peer reviewers were asked whether the requirements of the *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* described above, had been fulfilled. Third, the peer reviewers were asked whether the Administrator's interpretation of the evidence for the addition of acute traumatic injury was appropriate and whether it supported the decision to propose adding acute traumatic injury to the List.

Identification of Other Studies To Support the Administrator's Determination

All three acute traumatic injury peer reviewers indicated that they were unaware of any additional studies concerning acute traumatic injury that should have been considered by the Administrator. One reviewer suggested that a complete list of citations that were excluded from the ADS's review as not relevant should have been provided to reviewers. The Administrator agrees to make the full list of citations identified in the literature review as well as excluded scientific papers available to reviewers in future rule-related peer reviews.[27]

Administrator's Compliance With Established Policy and Procedures To Add Non-Cancer Health Conditions to the List of WTC-Related Health Conditions

Two of the acute traumatic injury peer reviewers found that the requirements of the policy had been fulfilled. One reviewer asked about the intent of describing the studies discussed in the assessment as "direct observational studies rather than epidemiologic studies," further asking whether it meant that causation is in question or that rates could not be computed.

Database	Search terms	Results
PubMed	("September 11 Terrorist Attacks" [Mesh] OR "World Trade Center" [TIAB] OR WTC [TIAB] OR "September 11" [TIAB]) AND ("Wounds and Injuries" [Mesh] OR "Occupational Injuries" [Mesh] OR "Cumultative Trauma Disorders" [Mesh] OR Injuries [TIAB]) From 2001/09/01 to 2014/12/31.	114
CINAHL	("MH Wounds and Injuries+") AND ("World Trade Center" OR "September 11")	36
Web of Science	("World Trade Center" OR "September 11") AND (Injury or injuries)	147
EMBASE	World Trade Center.mp. OR September 11.mp. AND exp injury/ (english language and embase and yr = "2001–Current").	191
Health & Safety Science Abstracts	("World Trade Center" OR "September 11") AND (injuries OR injury)	31
NIOSHTIC-2	World Trade Center (Title) AND Injury or Injuries (All Fields)	22

The October 2014 version of the WTC Health Program's policy and procedures on adding non-cancers to the List used to evaluate acute traumatic injury studies for the NPRM distinguished between those types of epidemiologic studies that can be used to identify causal associations between exposures and health outcomes such as diseases, and those studies that can be used to identify causal associations between exposures and health outcomes such as cases of injury.[28] The terminology "direct observational studies" was an attempt to use plain language to describe the types of studies that could provide relevant evidence of a causal association between 9/11 exposures and a health outcome, such as an injury. However, rather than making the intent clear, it appears that the term may be confusing. By describing the studies used to identify certain health outcomes as "direct observational studies," the WTC Health Program intended to describe studies which are more often referred to as "descriptive epidemiologic studies" within the scientific community. As discussed above, recent amendments to the policy clarify the terminology to mitigate confusion regarding the types of information sources the WTC Health Program uses to support the addition of certain health conditions to the List.[29]

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[26] Gisela Banauch, Mark Brantley, Gabriel Izbicki, *et al., Accelerated Spirometric Decline in New York City Firefighters with α1 –Antitrypsin Deficiency,* CHEST 2010;138(5):1116–1124.

[27] The table below provides the search strings used to conduct the literature search; the full list of citations identified by the literature search conducted by the ADS is not provided here. The NPRM incorrectly identified search terms used in the literature review (80 FR 54746 at 54752); the terms identified in the NPRM were instead terms used to develop cost estimates for the Executive Order 12866 and Executive Order 13563 analysis in Section VIII.A.

[28] *See* John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* revised Oct. 21, 2014, *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.*

[29] John Howard, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions,* revised May 11, 2016, *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf.*

In accordance with both the previous and current policy and procedures on adding non-cancers to the List used to develop this rulemaking, the ADS searched published, peer-reviewed epidemiologic studies of acute traumatic injuries in the 9/11-exposed population, including studies referred to in the October 2014 policy as "direct observational studies." The epidemiologic studies reviewed for this rulemaking to support the addition of WTC-related acute traumatic injury to the List document that outcomes occurred because of the 9/11 exposures and, thus, can be used to establish a causal association between the 9/11-related event, such as being struck by falling debris, and the injury, such as a broken arm. The studies reviewed allow the Administrator to conclude that certain types of acute traumatic injury suffered by WTC responders and survivors were sustained during or in the aftermath of the September 11, 2001, terrorist attacks and find that the evidence provides substantial support for a causal association between acute traumatic injury and 9/11 exposures.

The reviewer also found it difficult to assess adherence to the policy because of a perceived lack of clarity with regard to the scope of the Administrator's inquiry and suggested that injuries should be identified as "acute," "subacute," and "chronic." The reviewer further questioned the distinction between a broad understanding of injuries which are musculoskeletal in nature and the Administrator's definition of "acute traumatic injury" and suggested the removal of a statement found in the NPRM characterizing musculoskeletal disorders as distinct from acute traumatic injuries, pointing out that many of the types of acute traumatic injury identified by the Administrator are musculoskeletal in nature. The reviewer suggested that the Administrator should have better clarified the distinction between acute and chronic traumatic injury (injuries caused by multiple exposures over time) and recommends that such a discussion be added to the analysis in the NPRM. Without this more robust discussion, the reviewer questioned how the definition of acute traumatic injury will be applied, particularly with regard to the timing of initial medical care post-injury, diagnosis of head trauma, treatment of chronic pain, medically associated health conditions, and pre-existing injuries.

The term "WTC-related musculoskeletal disorder" is defined in the PHS Act and statements in the NPRM regarding "musculoskeletal disorders" are based on, and are consistent with, the statutory definition which sets out a clear standard for identifying chronic or recurrent disorders of the musculoskeletal system, caused by heavy lifting or repetitive strain.[30] In contrast to the term "chronic traumatic injury," used by the reviewer, the Administrator defines a "WTC-related acute traumatic injury" as an injury that occurred suddenly during one incident involving exposure to an external event. The new definition of "WTC-related acute traumatic injury" may capture musculoskeletal injuries which do not meet the statutory definition of "WTC-related musculoskeletal disorder." The purpose of this action is to provide Program coverage for those injuries that do not meet the existing definition of WTC-related musculoskeletal disorder, such as, for example, those not caused by heavy lifting or repetitive strain.

The reviewer's detailed questions regarding how the definition of WTC-related acute traumatic injury will be operationalized will be answered in forthcoming guidance to CCE and NPN physicians. Each WTC Health Program member's health condition will be evaluated in accordance with the Program's published policies and procedures.

Administrator's Interpretation of Evidence for the Addition of Acute Traumatic Injuries

Two of the acute traumatic injury peer reviewers found the Administrator's interpretation of the available data to be appropriate.

One reviewer found the presentation of data to be confusing and the Administrator's final determination concerning the addition of acute traumatic injury to the List unclear with regard to its scope. The reviewer acknowledged that the ADS may have encountered difficulties obtaining evidence of injury severity and outcomes, which the reviewer felt were crucial to a true understanding of the chronicity or level of injury severity, and disagreed with the Administrator's conclusion regarding the types of acute traumatic injuries identified by the literature. According to the reviewer, the documentation of extreme injuries in the surveillance literature should not lead to conclusions regarding the types of injuries and their outcomes. The reviewer suggested various edits to the Administrator's assessment of the data, published in the NPRM, to either omit the word "severe" in reference to burns, or define it in terms of total body surface area and burn depth, and to clarify that the severity of injury could not be ascertained from the studies reviewed. The reviewer disagreed with the Administrator's conclusion that an eye injury, such as corneal abrasion, could be caused by an exposure to energy. Ultimately, the reviewer disagreed with the Administrator's proposed definition of acute traumatic injury and instead suggested that the Administrator define trauma as a cause of injury. Such injuries would include all types of traumatic events regardless of the body area or organ system injured. Examples include, but are not limited to head injury, burns, ocular injury, fractures, and tendon and other soft-tissue injuries.

In his evaluation of the data quality, the Administrator acknowledged that some information was not captured by the studies, and although he agrees that a full understanding of the severity of injuries suffered on or after September 11, 2001 may not be gleaned from the studies reviewed, he found that the data were sufficient to corroborate the findings of the CCEs and Data Centers and to develop a broad definition of "acute traumatic injury." The use of the word "severe" to describe burns was intended to reflect the request made by the CCE and Data Center directors, which referred to the types of injuries they were seeing as "significant" and "severe." As discussed in the NPRM preamble, the types of injuries described by the CCE and Data Center directors are those that are most likely to result in the need for the services provided by the WTC Health Program and thus are those that the Administrator intended to capture by adding this health condition to the List. However, the Administrator agrees that the word "severe" is not defined, either in the surveillance literature or by the Administrator in the NPRM preamble. The word "severe," as used to describe burns in the proposed definition of "acute traumatic injury," is stricken from the final regulatory text in response to this review.

The Administrator's intent is to add coverage of acute traumatic injury caused by 9/11 exposures. The reviewer's proposal incorporates all types of trauma, including chronic or recurrent disorders of the musculoskeletal system, caused by heavy lifting or repetitive strain, which are already covered for responders by the Program under the PHS Act's definition of "WTC-related musculoskeletal disorder." The edits proposed by the reviewer would not substantively alter the evaluation of the available literature or the Administrator's determination that the available scientific evidence supports adding WTC-related acute traumatic injury to the List.

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[30] Pursuant to sec. 3312(a)(4) of the PHS Act, "WTC-related musculoskeletal disorder" means a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks. For a WTC responder who received any treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003, eligible musculoskeletal disorders include: (i) Low back pain; (ii) Carpal tunnel syndrome [CTS]; (iii) Other musculoskeletal disorders. *See also* 42 CFR 88.1.

The Administrator based the regulatory definition of WTC-related acute traumatic injury on several established definitions, including the definition used by the NIOSH Traumatic Injury Program which was accepted by the National Academy of Sciences in 2008.[31] The regulatory definition is intended to address the etiology of the injury—that is, that it occurred as the result of a single incident. The incident, characterized by an "exposure to energy," could include the movement of dust particles across the surface of the cornea, and result in an eye injury, such as a corneal abrasion. Because subacute and chronic conditions describe further stages after the injury has occurred, adding these additional categorizations to the regulatory definition is unnecessary. The regulatory definition includes all acute injuries that meet the definition.

The reviewer also asserted that the September 11, 2003 treatment cut-off "seems excessively long for most types of acute trauma but too short for others," and is not supported by evidence. According to the reviewer, the data presented in the NPRM demonstrated that most acute traumatic injuries were treated within hours of being sustained, although traumatic brain injuries may not have been identified for years after the event.

The Administrator agrees that the evidence reviewed in the NPRM demonstrates that most acute traumatic injuries were treated soon after they were sustained. The end date for initial treatment is well beyond the response and recovery period for the three sites and generously allows for delays in seeking treatment. The Administrator acknowledges that most responders and survivors who sustained acute traumatic injuries would have received medical treatment long before September 11, 2003. The reviewer also accurately points out that numerous cases of traumatic brain injury (TBI) identified in the Rutland-Brown paper, included in the ADS's review published in the NPRM,[32] were not diagnosed as TBI within 3 years of the exposure. However, each of these persons was admitted to a hospital for injuries/illnesses related to the September 11, 2001, terrorist attacks and treated for head injury or major trauma, but was not diagnosed with TBI at the time they initially received medical care. The regulatory text does not require the member to have been diagnosed with a TBI on or before September 11, 2003, only that he or she received medical attention for an acute traumatic injury by that date. When operationalizing the addition of WTC-related acute traumatic injury, the Program will ensure that this is clearly explained to the CCEs and the NPN. The Administrator finds that the September 11, 2003 deadline is consistent with the evidence presented in the NPRM and is neither too long nor too short for its intended purpose of offering a reasonable amount of time in which to expect that an injury sustained on or after September 11, 2001 was treated. As discussed in the NPRM preamble, the decision was made to set the end-date because this was the date used to identify traumatic injuries eligible for treatment in the WTC Medical Monitoring and Treatment Program that preceded the WTC Health Program; moreover, the PHS Act uses this date as the treatment cut-off date to identify musculoskeletal disorders eligible for certification in responders.

Finally, the reviewer found that the examples of acute traumatic injuries identified in the NPRM Summary of Proposed Rule were unnecessary and confusing, appearing to attribute "causality to non-causal events." With regard to the examples of acute traumatic injury offered in the Summary of Proposed Rule, the Administrator agrees; the sentence could be construed as not differentiating between causes and outcomes. This language was used in the Summary of Proposed Rule section of the NPRM preamble not to attribute causation, but to illustrate the types of injuries that the Program would find "acute" and "traumatic." This language is removed from the final rule and the Administrator will provide Program guidance to CCE and NPN physicians on the identification of acute traumatic injuries that could be considered WTC-related.

B. Public Comment

Support for Acute Traumatic Injuries

Nearly all commenters expressed support for the addition of acute traumatic injury to the List. Although some submissions only addressed the addition of new-onset COPD, no commenters opposed the addition of acute traumatic injury.

Acute Traumatic Injury Medical Care Cut-off Date

One commenter offered support for the September 11, 2003 cut-off date. Three commenters expressed concern about the proposal to require responders or survivors who seek certification for an acute traumatic injury to have received medical care prior to September 11, 2003. Commenters suggested that the time period should be replaced with a simple requirement that the injury had to have been documented in medical records, even if the member did not receive treatment for the acute traumatic injury. Alternatively, commenters suggested that the September 11, 2003 date should be pushed back to 2004 to accommodate those responders or survivors who may not have recognized the extent of their injuries and, therefore, did not seek treatment prior to September 11, 2003, or those who either lost their medical records or can no longer obtain them from emergency rooms or private physicians.

Requiring only that the acute traumatic injury appear in the WTC Health Program member's medical record, regardless of treatment, would not accomplish the Administrator's intent to ensure, to the extent possible, that the member's acute traumatic injury was sustained during or in the aftermath of the September 11, 2001, terrorist attacks. By requiring that members demonstrate that they received timely treatment for acute traumatic injuries, the Administrator will better be able to establish a medical history linking the member's current chronic injury or medically associated health condition to an acute traumatic injury that resulted from that individual's 9/11 exposure. As discussed above, the Administrator has determined that the September 11, 2003 cut-off date for medical treatment is supported, and has not identified any evidence to support extending the cut-off date for another year.

Medically Associated Health Conditions

Two submissions addressed the matter of health conditions medically associated with WTC-related acute traumatic injury. One commenter offered a first-hand account of the health conditions he incurred as a result of the September 11, 2001, terrorist attacks, suggesting that he still suffers from medically associated conditions. The other commenter expressed concern that health conditions medically associated with WTC-related health conditions were not specifically addressed in the NPRM, particularly with regard to acute traumatic injury.

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[31] Committee to Review the NIOSH Traumatic Injury Research Program, Institute of Medicine and National Research Council, *Traumatic Injury Research at NIOSH,* 2009, *http://www.nap.edu/catalog/12459/traumatic-injury-research-at-niosh.*

[32] *See* 80 FR 54746 at 54753.

Health conditions medically associated with WTC-related health conditions were briefly addressed in the NPRM.[33] The Administrator expects that many Program members who experienced an acute traumatic injury may no longer be dealing with the primary injury, but are in need of ongoing medical care for chronic conditions stemming from the original injury. For example, a WTC responder may have suffered a head trauma during response activities which was resolved years ago, but may still be coping with the long-term effects of TBI. Once WTC-related acute traumatic injury is added to the List, the WTC responder's TBI may be eligible for certification as a condition medically associated with the WTC-related acute traumatic injury, head trauma. Health conditions medically associated with a WTC-related health condition are determined by the Program on a case-by-case basis, in accordance with published Program regulations and policies and procedures.

VII. How To Get Help for WTC-Related Health Conditions

One commenter described suffering from untreated, chronic health issues that may stem from work at Ground Zero. Although this comment was not directly related to the rulemaking, the Administrator wants to remind individuals who may have responded to or survived the September 11, 2001, terrorist attacks, that the WTC Health Program provides medical monitoring and treatment for WTC-related health conditions. An individual may apply to become a WTC Health Program member by filling out the appropriate application, available on the Program's Web site here: *http://www.cdc.gov/wtc/apply.html* (call 1–888–982–4748 to discuss the application process).

VIII. Summary of Final Rule

For the reasons discussed above and in the NPRM, the Administrator amends 42 CFR 88.1, "List of WTC-related health conditions," paragraph (1)(v), to add "new-onset" COPD to the existing "WTC-exacerbated chronic obstructive pulmonary disease (COPD)." This will permit the WTC Health Program to certify cases of COPD determined to have been caused or contributed to by 9/11 exposures (considered "new-onset" cases), in addition to those cases of COPD which were exacerbated by 9/11 exposures and which are already included on the List.

For the reasons discussed above, the Administrator also adds "WTC-related acute traumatic injury" to the List for WTC responders and screening- and certified-eligible survivors who received medical treatment for such an injury on or before September 11, 2003. The term "WTC-related acute traumatic injury" is defined as a type of injury characterized by physical damage to a person's body that must have been caused by and occurred immediately after exposure to hazards or adverse conditions characterized by a one-time exposure to energy resulting from the terrorist attacks or their aftermath. This requirement is intended to distinguish these types of injuries from musculoskeletal disorders, which are already included on the List of WTC-Related Health Conditions. As required by statute, WTC-related musculoskeletal disorders are considered to be caused by repetitive motion or heavy lifting; the health condition "WTC-related acute traumatic injury" requires a demonstration of causation by a specific event or incident. Symptoms of acute traumatic injuries may not immediately manifest after the specific event or incident. The Administrator will issue guidance to CCE and NPN physicians on the identification of WTC-related acute traumatic injury. WTC-related acute traumatic injury includes, but is not limited to the following: Eye injury; burn; head trauma; fracture; tendon tear; complex sprain; and other similar injuries. The term "WTC-related" was not included in the term proposed in the NPRM; however, the Administrator finds that adding it would result in no substantive change from the proposed rule. It would be in keeping with the existing definition of "WTC-related musculoskeletal disorder" and would also signal that this language was developed specifically for the purposes of the WTC Health Program. Finally, to clarify the Administrator's intent, the regulatory text is reorganized slightly from that which was proposed. The reorganization has no substantive effect.

IX. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This rulemaking has been determined not to be a "significant regulatory action" under section 3(f) of Executive Order 12866. This rule adds new-onset COPD[34] and WTC-related acute traumatic injury to the List of WTC-Related Health Conditions established in 42 CFR 88.1. This rulemaking is estimated to cost the WTC Health Program from $4,602,162 to $5,666,713 annually, between 2016 and 2019.[35] All of the costs to the WTC Health Program will be transfers due to the implementation of provisions of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148) on January 1, 2014. This rulemaking has not been reviewed by the Office of Management and Budget (OMB). The rule would not interfere with State, local, and Tribal governments in the exercise of their governmental functions.

Population Estimates

As of December 1, 2015, the WTC Health Program had enrolled 64,384 responders and 9,358 survivors (73,742 total). Of that total population, 56,207 responders and 4,772 survivors (60,979 total) were participants in previous WTC medical programs and were 'grandfathered' into the WTC Health Program established by Title XXXIII of the PHS Act.[36] From July 1, 2011 to

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[33] *See* 80 FR 54746 at 54756.

[34] WTC-exacerbated COPD is a statutorily covered condition pursuant to PHS Act, sec. 3312(a)(3)(A)(v); this NPRM proposes to add new-onset COPD occurring after 9/11 exposures.

[35] The low cost estimate reflects the 2016 undiscounted new-onset COPD treatment cost estimate using WTC Health Program data from Table 5 and the 2016 undiscounted WTC-related acute traumatic injury treatment cost estimate from Table 6. The high cost estimate reflects the high new-onset COPD treatment cost estimate for 2019, discounted at 3 percent, using data from Leigh *et al.* from Table 5 and the WTC-related acute traumatic injury treatment cost estimate for 2019, discounted at 3 percent, from Table 6. Future cost and prevalence estimates are discounted at 3% and 7% in accordance with OMB Circular A–94, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs.* The estimates are discounted in order to compute net present value.

[36] These grandfathered members were enrolled without having to complete a new member application when the WTC Health Program started on July 1, 2011 and are referred to in the WTC Health Program regulations in 42 CFR part 88 as "currently identified responders" and "currently identified survivors."

December 1, 2015, 8,177 new responders and 4,586 new survivors (12,763 total) enrolled in the WTC Health Program. For the purpose of calculating a baseline estimate of new-onset COPD and WTC-related acute traumatic injury prevalence, the Administrator projected that new enrollment would be approximately 4,000 per year (2,800 new responders and 1,200 new survivors), based on the trend in enrollees through December 1, 2015.

CCE or NPN physicians will conduct medical assessments for patients as appropriate and make a determination, which the Administrator will then use to certify or not certify the health condition (in this case, new-onset COPD or a type of WTC-related acute traumatic injury) for treatment by the WTC Health Program. However, for the purpose of this analysis, the Administrator has assumed that all diagnosed cases of new-onset COPD and acute traumatic injury will be certified for treatment by the WTC Health Program. Finally, because there are no existing data on new-onset COPD rates related to 9/11 exposures at either the Pentagon or Shanksville, Pennsylvania sites, and only limited data on acute traumatic injuries at the Pentagon, the Administrator has used only data from studies of individuals who were responders or survivors in the New York City area.

Prevalence of New-Onset COPD

To estimate the number of potential cases of WTC-related new-onset COPD to be certified for treatment by the WTC Health Program, we first subtracted the number of current members certified for an obstructive airways disease (OAD), including WTC-exacerbated COPD, from the total number of members.[37] We then reviewed the surveillance literature to determine a prevalence rate for new-onset COPD among the non-OAD certified members. In studies of FDNY members with known pre-9/11 health status and high WTC exposure, Aldrich *et al.* reported that 2 percent of FDNY firefighters had an FEV1% below 70 percent of predicted[38] at year 1 after September 11, 2001 (a proportion that doubled 6.5 years later), and Webber *et al.*[39] reported an approximate 4 percent prevalence of new-onset, self-reported, physician-diagnosed COPD/emphysema nearly ten years after rescue/recovery efforts at the WTC site. Because pre-9/11 health records were not available in studies of WTC survivors, the Administrator has determined that the 4 percent prevalence of new-onset COPD will be applied to survivor estimates as well.[40] We applied the 4 percent prevalence to the number of remaining members and also to the projected annual enrollment of 4,000 new members to estimate the number of potential WTC-related new-onset COPD cases in 2016. (See Table 1, below)

TABLE 1—ESTIMATED PREVALENCE OF 2016–2019 NEW-ONSET COPD CASES

	2016	2017	2018	2019
Responders	2,106	2,218	2,330	2,442
Survivors	306	354	402	450
Total	2,412	2,572	2,732	2,892

Prevalence of WTC-Related Acute Traumatic Injury

While this rulemaking would make acute traumatic injury eligible for certification, the Administrator assumes that the conditions most likely to receive treatment within the WTC Health Program will be those medically associated conditions which are the long-term consequences of the certified WTC-related acute traumatic injury. Health conditions medically associated with WTC-related health conditions are determined on a case-by-case basis in accordance with WTC Health Program regulations and policies and procedures.[41] Examples of such health conditions medically associated with a WTC-related acute traumatic injury may include chronic back pain caused by vertebrae fractures, chronic peripheral neuropathy due to severe burns, and problems with executive brain function due to closed head injuries.

Although we were able to estimate from the surveillance literature the number of responders and survivors who received medical treatment for acute traumatic injuries on or in the aftermath of September 11, 2001, we do not know the number of individuals who still experience health problems because of those traumatic injuries and are in need of chronic care. To project this, we estimated the number of persons in the responder and survivor populations with WTC-related acute traumatic injury by deriving estimates from the Berrios-Torres *et al.*,[42] Banauch *et al.*,[43] Perritt *et al.*,[44] and NYCDOH studies.[45] Using the estimated prevalence for injury types, we then calculated the prevalence for these injuries among the responder[46] and survivor[47] populations. We applied that prevalence to the number of current and expected WTC Health Program members to find the number of individuals who may have suffered a WTC-related acute traumatic injury. Next, in order to estimate the proportion of those in the responder and survivor populations who suffered WTC-related acute traumatic injuries that require chronic care, we assumed that all patients with permanent partial and permanent total impairment caused by acute traumatic injuries will require chronic medical care and will enroll in the WTC Health Program. The National Safety Council estimated that 3.8 percent of non-fatal disabling injuries[48] are associated with permanent partial or permanent total impairment.[49] We applied that estimate to the estimated number of current and expected WTC Health Program members who may have suffered a WTC-related acute traumatic injury to determine the number of individuals with WTC-related acute traumatic injury who are in need of chronic care. (*See* Table 2, below.)

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[37] Cases of COPD diagnosed prior to September 11, 2001, are presumed to be eligible for coverage as WTC-exacerbated COPD and therefore would not need coverage under new-onset COPD. Members already certified for an obstructive airway disease are also removed from the analysis because any progression to COPD (*i.e.*, airflow limitation not fully reversible with bronchodilator) from their current certified WTC-related OAD condition could be considered a health condition medically-associated with the certified WTC-related OAD condition. *See* John Howard, Administrator of the WTC Health Program, *Health Conditions Medically Associated with World Trade Center-Related Health Conditions*, revised Nov. 7, 2014, *http://www.cdc.gov/wtc/pdfs/WTCHPMedically%20AssociatedHealthConditions7November2014.pdf.*

[38] The term of art "percent of predicted" means that the proportion of the patient's vital capacity expired in 1 second of forced expiration (FEV1%) is less than the predicted average FEV1% in the population for a person of similar age, sex, and body composition. FEV1% predicted is a marker for severity of airway obstruction. In the setting of post-bronchodilator FEV1/FVC ≤0.7, FEV1% predicted ≥80 indicates mild COPD; 50–80, moderate; 30–50, severe, and <30, very severe. *See* American Thoracic Society COPD Guidelines, *Spirometric Classification*, 2015, *http://www.thoracic.org/copd-guidelines/for-health-professionals/definition-diagnosis-and-staging/spirometric-classification.php.*

[39] Mayris Webber, Michelle Glaser, Jessica Weakley, *et al., Physician-Diagnosed Respiratory Conditions and Mental Health Symptoms 7–9 Years Following the World Trade Center Disaster*, AJIM 2011;54:661–671.

[40] The 4 percent prevalence of new-onset COPD that was observed among firefighters was used to estimate the number of expected cases of new-onset COPD in the entire exposed cohort and may result in an overestimation because of the differences in initial exposure intensity between responders and survivors.

[41] John Howard, Administrator of the WTC Health Program, *Health Conditions Medically Associated with World Trade Center-Related Health Conditions*, revised Nov. 7, 2014, *http://www.cdc.gov/wtc/pdfs/WTCHPMedically%20AssociatedHealthConditions7November2014.pdf.*

[42] Sandra Berrios-Torres, Jane Greenko, Michael Philips, *et al., World Trade Center Rescue Worker Injury and Illness Surveillance, New York, 2001*, Am J Prev Med 2003;25(2):79–87.

[43] G Banauch, M McLaughlin, R Hirschhorn, *et al., Injuries and Illnesses among New York City Fire Department Rescue Workers after Responding to the World Trade Center Attacks*, MMWR Sept. 11, 2002;51(Special Issue):1–5.

[44] Kara Perritt, Winifred Boal, The Helix Group Inc., *Injuries and Illnesses Treated at the World Trade Center, 14 September–20 November 2001*, Prehosp Disaster Med 2005;20(3).

TABLE 2—ESTIMATED PREVALENCE OF 2016–2019 WTC-RELATED ACUTE TRAUMATIC INJURY CASES

	2016	2017	2018	2019
Responders	80	83	86	89
Survivors	10	12	13	14
Total	90	95	99	103

Costs of COPD Treatment

The Administrator estimated the medical treatment costs associated with new-onset COPD in this rulemaking, using the methods described below, to be between $1,665 and $1,930 per case in 2014.

The low estimate, $1,665 per case, was based on WTC Health Program costs associated with the treatment of WTC-exacerbated COPD for the period October 1, 2013 through September 30, 2014. These medical costs include both medical services and pharmaceuticals.[50]

The high estimate, $1,930 per case, was based on a study by Leigh *et al.*[51] The authors estimated the cost of occupational COPD by aggregating and analyzing national data sets collected by the National Center for Health Statistics, the Health Care Financing Administration, and other government agencies and private firms. They concluded that there were an estimated 2,395,650 occupational cases of COPD in 1996 that resulted in medical costs estimated at $2.425 billion. Medical costs included payments to hospitals, physicians, nursing homes, and vendors of medical supplies, including oxygen, and also included the cost of pharmaceuticals.[52] The medical cost per case was about $1,012 in 1996 dollars or about $1,930 in 2014 dollars, after adjusting for inflation using the Medical Consumer Price Index for all urban consumers.[53]

Table 3 below shows medical treatment cost estimates per COPD case in 2016–2019:

TABLE 3—ESTIMATED MEDICAL TREATMENT COSTS PER NEW-ONSET COPD CASE DURING 2016–2019 IN 2014 DOLLARS

Source	Year	Undiscounted	Discounted 3%	Discounted 7%
WTC Health Program	2016	$1,665		
	2017	1,665	$1,617	$1,556
	2018	1,665	1,569	1,454
	2019	1,665	1,524	1,359
Leigh *et al.*	2016	1,930		
	2017	1,930	1,874	1,804
	2018	1,930	1,819	1,686
	2019	1,930	1,766	1,575

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[45] New York City Department of Health, *Rapid Assessment of Injuries Among Survivors of the Terrorist Attack on the World Trade Center—New York City, September 2001*, MMWR Jan. 11, 2002;51(01);1–5.

[46] The responder estimate is subject to two main assumptions. First, Banauch *et al.* reported on FDNY members from September 11 to December 10, 2001, and we assume no additional injuries from December 11, 2001 until the site was closed in July 2002. The time period reported on by Banauch *et al.* likely encompasses a large majority of the injuries suffered by FDNY members. Second, Perritt *et al.* did not report directly on closed head injuries; therefore the number of closed head injuries reported by Berrios-Torres *et al.* for responders is used.

[47] We estimate the survivor prevalence from the NYCDOH study reports on survivors during the period from September 11–13, 2001. Although we understand that this reporting period likely encompasses a majority of the survivors who were injured, because the number of cases is based on those survivors who were treated for injuries only within the first 48 hours after the terrorist attacks, the reported number of cases likely underestimates the total number of survivors who sustained acute traumatic injuries as a result of the September 11, 2001, terrorist attacks.

[48] In 2011, the National Safety Council replaced the term "disabling injury" with "medically consulted injury." *See* National Safety Council, *Injury Facts*, 2014.

[49] A non-fatal disabling injury is one which results in some degree of permanent impairment or renders the injured person unable to effectively perform his regular duties or activities for a full day beyond the day of the injury. National Safety Council, *Injury Facts*, 1986.

[50] Pharmaceutical costs are estimated to be approximately 38 percent of total treatment costs.

[51] J. Paul Leigh, Patrick Romano, Marc Schenker, Kathleen Kreiss, *Costs of Occupational COPD and Asthma*, CHEST 2002;121(1):264–272.

[52] Screening costs are not included because the U.S. Preventive Services Task Force does not recommend screening for COPD. *See Screening for Chronic Obstructive Pulmonary Disease Using Spirometry, http://www.uspreventiveservicestaskforce.org/uspstf/uspscopd.htm.*

[53] Bureau of Labor Statistics, *Consumer Price Index for All Urban Consumers: Medical Care, https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419.*

Costs of WTC-Related Acute Traumatic Injury Treatment

The Administrator estimated the medical treatment costs associated with WTC-related acute traumatic injury in this rulemaking using the methods described below. Because it is not possible to identify all possible types of acute traumatic injury for which a WTC responder or survivor might seek certification, we have identified several types of acute traumatic injury that may be representative of those types of acute traumatic injuries that might be certified by the WTC Health Program. Representative examples of types of WTC-related acute traumatic injury include closed head injuries, burns, fractures, strains and sprains, orthopedic injuries (*e.g.*, meniscus tear), ocular injuries, and crush injuries. The WTC Health Program estimates the cost of providing medical treatment for WTC-related acute traumatic injury to be around $11,216 per case in 2014 dollars.

This cost figure was based on a study by the National Council on Compensation Insurance (NCCI).[54] The data source used in this study was NCCI's Medical Data Call (MDC). The MDC captures transaction-level detail on workers' compensation medical bills processed on or after July 1, 2010, including dates of service, charges, payments, procedure codes, and diagnosis codes; pharmaceutical costs are also included. The data used in this study were evaluated as of March 2013 for:

- Long-term medical services provided in 2011 and 2012 (*i.e.*, 20 to 30 years post injury)
- Injuries occurring between 1983 and 1990
- Claimants with dates of birth between 1920 and 1970
- States for which NCCI collects MDC[55]

For individuals born during 1951–1970, the medical cost per case was about $11,216 in 2014 dollars, after adjusting for inflation using the Medical Consumer Price Index for all urban consumers.[56]

Table 4 below shows medical treatment cost estimates per acute traumatic injury case in 2016–2019:

TABLE 4—ESTIMATED MEDICAL TREATMENT COSTS PER WTC-RELATED ACUTE TRAUMATIC INJURY CASE DURING 2016–2019 IN 2014 DOLLARS

Source	Year	Undiscounted	Discounted 3%	Discounted 7%
NCCI	2016	$11,216		
	2017	11,216	$10,890	$10,482
	2018	11,216	10,572	9,796
	2019	11,216	10,264	9,156

Summary of Costs

This rulemaking is estimated to cost the WTC Health Program from $4,602,162 to $5,666,713 annually, between 2016 and 2019.[57] The analysis above offers an assumption about the number of individuals who might enroll in the WTC Health Program and estimates the number of new-onset COPD and WTC-related acute traumatic injury cases and the resulting estimated treatment costs to the WTC Health Program. For the purpose of computing the treatment costs for new-onset COPD and WTC-related acute traumatic injury, the Administrator assumed that all of the individuals who are diagnosed with either condition will be certified by the WTC Health Program for treatment services. In the calculations found in Tables 5 and 6, below, estimated treatment costs were applied to the estimated number of cases of new-onset COPD and WTC-related acute traumatic injury. We assumed that 9 percent of new-onset COPD costs and 12 percent of WTC-related acute traumatic injury costs for responders may be covered by workers' compensation each year; accordingly, we adjusted only the responder estimates to clarify that 91 percent of COPD costs and 88 percent of WTC-related acute traumatic injury costs will be paid by the WTC Health Program.[58] This analysis does not include administrative costs associated with certifying additional diagnoses of new-onset COPD or WTC-related acute traumatic injury that are WTC-related health conditions that might result from this action. Those costs were addressed in the interim final rule that established regulations for the WTC Health Program.[59]

Since the implementation of provisions of the ACA on January 1, 2014, all of the members and future members are assumed to have or have access to medical insurance coverage other than through the WTC Health Program. Therefore, all treatment costs to be paid by the WTC Health Program through 2019 are considered transfers. Tables 5 and 6 describe the estimated allocation of WTC Health Program transfer payments.

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[54] David Colón, *The Impact of Claimant Age on Late-Term Medical Costs,* NCCI Research brief, Oct. 2014, *https://www.ncci.com/documents/Impact-Claimant-Age-Late-Term-Med-Costs.pdf.*

[55] AK, AL, AR, AZ, CO, CT, DC, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NV, NY, OK, OR, RI, SC, SD, TN, UT, VA, VT, WI, and WV.

[56] Bureau of Labor Statistics, *Consumer Price Index for All Urban Consumers: Medical Care, https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419.*

[57] The low cost estimate reflects the 2016 undiscounted new-onset COPD treatment cost estimate using WTC Health Program data from Table 5 and the 2016 undiscounted WTC-related acute traumatic injury treatment cost estimate from Table 6. The high cost estimate reflects the high new-onset COPD treatment cost estimate for 2019, discounted at 3 percent, using data from Leigh *et al.* from Table 5 and the WTC-related acute traumatic injury treatment cost estimate for 2019, discounted at 3 percent, from Table 6. NB: The cost estimate provided in the NPRM included only the years 2015 and 2016, and costs were provided in the aggregate.

[58] Workers' compensation rates are derived from WTC Health Program data. *See* WTC Health Program, *Policy and Procedures for Recoupment and Coordination of Benefits: Workers' Compensation Payment,* revised Dec. 16, 2013, *http://www.cdc.gov/wtc/pdfs/WTCHP–PP-Recoupment-WComp-16-Dec-13.pdf.*

[59] 76 FR 38914 (July 1, 2011).

TABLE 5—MEDICAL TREATMENT COST FOR NEW-ONSET COPD CASES DURING 2016–2019 IN 2014 DOLLARS

Source (costs)	Year	Undiscounted	Discounted 3%	Discounted 7%
WTC Health Program	Responders			
	2016	$1,665 * 2,106 * .91 = $3,190,906.		
	2017	$1,665 * 2,218 * .91 = $3,360,603.	$1,617 * 2,218 * .91 = $3,263,720.	$1,556 * 2,218 * .91 = $3,140,599
	2018	$1,665 * 2,330 * .91 = $3,530,300.	$1,569 * 2,330 * .91 = $3,326,751.	$1,454 * 2,330 * .91 = $3,082,916
	2019	$1,665 * 2,442 * .91 = $3,699,996.	$1,524 * 2,442 * .91 = $3,386,663.	$1,359 * 2,442 * .91 = $3,019,997
	Survivors			
	2016	$1,665 * 306 = $509,490.		
	2017	$1,665 * 354 = $589,410	$1,874 * 354 = $663,396	$1,804 * 354 = $638,616
	2018	$1,665 * 402 = $669,330	$1,819 * 402 = $731,238	$1,686 * 402 = $677,772
	2019	$1,665 * 450 = $749,250	$1,766 * 450 = $794,700	$1,575 * 450 = $708,750
	Total (low estimates)			
	2016	$3,700,396.		
	2017	$3,950,013	$3,927,116	$3,779,215
	2018	$4,199,630	$4,057,989	$3,760,688
	2019	$4,449,246	$4,181,363	$3,728,747
Leigh *et al.*	Responders			
	2016	$1,930 * 2,106 * .91 = $3,698,768.		
	2017	$1,930 * 2,218 * .91 = $3,895,473.	$1,874 * 2,218 * .91 = $3,782,444.	$1,804 * 2,218 * .91 = $3,641,158
	2018	$1,930 * 2,330 * .91 = $4,092,179.	$1,819 * 2,330 * .91 = $3,856,826.	$1,686 * 2,330 * .91 = $3,574,826
	2019	$1,930 * 2,442 * .91 = $4,288,885.	$1,766 * 2,442 * .91 = $3,924,441.	$1,575 * 2,442 * .91 = $3,499,997
	Survivors			
	2016	$1,930 * 306 = $590,580.		
	2017	$1,930 * 354 = $683,220	$1,874 * 354 = $663,396	$1,804 * 354 = $638,616
	2018	$1,930 * 402 = $775,860	$1,819 * 402 = $731,238	$1,686 * 402 = $677,772
	2019	$1,930 * 450 = $868,500	$1,766 * 450 = $794,700	$1,575 * 450 = $708,750
	Total (high estimates)			
	2016	$4,289,348.		
	2017	$4,578,693	$4,445,840	$4,279,774
	2018	$4,868,039	$4,588,064	$4,252,598
	2019	$5,157,385	$4,719,141	$4,208,747

TABLE 6—MEDICAL TREATMENT COST FOR WTC-RELATED ACUTE TRAUMATIC INJURY CASES DURING 2016–2019 IN 2014 DOLLARS

Source (costs)	Year	Undiscounted	Discounted 3%	Discounted 7%
NCCI	Responders			
	2016	$11,216 * 80 * .88 = $789,606		
	2017	$11,216 * 83 * .88 = $819,217	$10,890 * 83 * .88 = $795,406	$10,482 * 83 * .88 = $765,605
	2018	$11,216 * 86 * .88 = $848,827	$10,572 * 86 * .88 = $800,089	$9,796 * 86 * .88 = $741,361
	2019	$11,216 * 89 * .88 = $878,437	$10,264 * 89 * .88 = $803,876	$9,156 * 89 * .88 = $717,098
	Survivors			
	2016	$11,216 * 10 = $112,160		
	2017	$11,216 * 12 = $134,592	$10,890 * 12 = $130,680	$10,482 * 12 = $125,784
	2018	$11,216 * 13 = $145,808	$10,572 * 13 = $137,436	$9,796 * 13 = $127,348
	2019	$11,216 * 14 = $157,024	$10,264 * 14 = $143,696	$9,156 * 14 = $128,184

TABLE 6—MEDICAL TREATMENT COST FOR WTC-RELATED ACUTE TRAUMATIC INJURY CASES DURING 2016–2019 IN 2014 DOLLARS—Continued

Source (costs)	Year	Undiscounted	Discounted 3%	Discounted 7%
	Total			
	2016	$901,766		
	2017	$953,809	$926,086	$891,389
	2018	$994,635	$937,525	$868,709
	2019	$1,035,461	$947,572	$845,282

Examination of Benefits (Health Impact)

This section describes qualitatively the potential benefits of the rule in terms of the expected improvements in the health and health-related quality of life of potential new-onset COPD or WTC-related acute traumatic injury patients treated through the WTC Health Program, compared to no treatment by the Program.

The Administrator does not have information on the health of the population that may have experienced 9/11 exposures and is not currently enrolled in the WTC Health Program. However, the Administrator assumes that all unenrolled responders and survivors are now covered by health insurance (due to the ACA) and may be receiving treatment outside the WTC Health Program.

Although the Administrator cannot quantify the benefits associated with the WTC Health Program, members with new-onset COPD or WTC-related acute traumatic injury would have improved access to care and, thereby, the Program should produce better treatment outcomes than in its absence. Under other insurance plans, patients may have deductibles, coinsurance, and copays, which impact access to care and timeliness of care. WTC Health Program members who are certified for these conditions would have first-dollar coverage and, therefore, are likely to seek care sooner when indicated, resulting in improved treatment outcomes.

Limitations

The analysis presented above was limited by the dearth of verifiable data on the new-onset COPD and acute traumatic injury status of responders and survivors who have yet to apply for enrollment in the WTC Health Program. Because of the limited data, the Administrator was not able to estimate benefits in terms of averted healthcare costs. Nor was the Administrator able to estimate indirect costs such as averted absenteeism, short and long-term disability, and productivity losses averted due to premature mortality.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The Administrator believes that this rule has "no significant economic impact upon a substantial number of small entities" within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. This rule does not contain any information collection requirements; thus, HHS has determined that the PRA does not apply to this rule.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 *et seq.*, HHS will report the promulgation of this rule to Congress prior to its effective date.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 *et seq.*, directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million in 1995 dollars by State, local, or Tribal governments in the aggregate, or by the private sector. However, the rule may result in an increase in the contribution made by New York City for treatment and monitoring, as required under the PHS Act, section 3331(d)(2).

F. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, "Civil Justice Reform," and will not unduly burden the Federal court system. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Administrator has reviewed this rule in accordance with Executive Order 13132 regarding Federalism, and has determined that it does not have "Federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, the Administrator has evaluated the environmental health and safety effects of this rule on children. The Administrator has determined that the rule would have no environmental health and safety effect on children.

I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, the Administrator has evaluated the effects of this rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal government administers or enforces. The Administrator has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 88

Administrative practice and procedure, Health care, Lung diseases, Mental health programs.

Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 88 as follows:

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

■ 1. The authority citation for part 88 is revised to read as follows:

Authority: 42 U.S.C. 300mm to 300mm–61, Pub. L. 111–347, 124 Stat. 3623, as amended by Pub. L. 114–113, 129 Stat. 2242.

■ 2. In § 88.1, under the definition "List of WTC-related health conditions," revise paragraph (1)(v) and add paragraph (5) to read as follows:

§ 88.1 Definitions.

* * * * *

List of WTC-Related Health Conditions

* * * * *

(1) * * *

(v) WTC-exacerbated and new-onset chronic obstructive pulmonary disease (COPD).

* * * * *

(5) Acute traumatic injuries:

(i) WTC-related acute traumatic injury: physical damage to the body caused by and occurring immediately after a one-time exposure to energy, such as heat, electricity, or impact from a crash or fall, resulting from a specific event or incident. For a WTC responder or screening-eligible or certified-eligible survivors who received any medical treatment for a WTC-related acute traumatic injury on or before September 11, 2003, such health condition includes:

(A) Eye injury.

(B) Burn.

(C) Head trauma.

(D) Fracture.

(E) Tendon tear.

(F) Complex sprain.

(G) Other similar acute traumatic injuries.

(ii) [Reserved]

Dated: June 27, 2016.

John Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–15799 Filed 7–1–16; 8:45 am]

BILLING CODE 4163–18–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[GN Docket No. 12–268, WT Docket Nos. 14–70, 05–211, RM–11395; FCC 15–80]

Updating Competitive Bidding Rules

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) approved on June 22, 2016, a revision to an approved information collection to implement modified collection requirements on FCC Form 601, Application for Radio Service Authorization, contained in the Part 1 Report and Order, Updating Competitive Bidding Rules, FCC 15–80. This document is consistent with the Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the requirements.

DATES: 47 CFR 1.2110(j), published at 80 FR 56764 on September 18, 2015 and revised FCC Form 601, are effective on July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Cathy Williams, *Cathy.Williams@fcc.gov,* (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on June 22, 2016, OMB approved the information collection requirements for FCC Form 601, FCC Application for Radio Service Authorization and 47 CFR 1.2110(j), which was contained in Report and Order, FCC 15–80. The OMB Control Number is 3060–0798. The Commission publishes this document as an announcement of the effective date of the requirements. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW., Washington, DC 20554. Please include the OMB Control Number, 3060–0798, in your correspondence. The Commission will also accept your comments via the Internet if you send them to *PRA@fcc.gov.* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on June 22, 2016, for the information collection requirements contained in information collection 3060–0798. Under 5 CFR 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–0798. The foregoing document is required by the Paperwork Reduction Act of 1995, Pub. L. 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0798.

OMB Approval Date: June 22, 2016.

OMB Expiration Date: June 30, 2019.

Title: FCC Application for Radio Service Authorization: Wireless Telecommunications Bureau

Public Safety and Homeland Security Bureau.

Form Number: FCC Form 601.

Respondents: Individuals and households; Business or other for profit entities; Not for profit institutions; and State, local or tribal government.

Number of Respondents and Responses: 253,320 respondents and 253,320 responses.

Estimated Hours per Response: 0.5–1.25 hours.

Frequency of Response: Recordkeeping requirement, third party disclosure requirement, On occasion reporting requirement and periodic reporting requirement.

Total Annual Burden: 222,055 hours.

Total Annual Costs: $71,306,250.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 152, 154, 154(i), 155(c), 157, 201, 202, 208, 214, 301, 302a, 303, 307, 308, 309, 310, 311, 314, 316, 319, 324, 331, 332, 333, 336, 534, 535 and 554.

Nature and Extent of Confidentiality: There is no need for confidentiality required with this collection of information.

Privacy Impact Assessment: Yes.

Needs and Uses: On July 20, 2015, the Commission released the *Part 1 R&O* in which it updated many of its Part 1 competitive bidding rules (*See Updating Part 1 Competitive Bidding Rules; Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions; Petition of DIRECTV Group, Inc. and EchoStar LLC for Expedited Rulemaking to Amend Section 1.2105(a)(2)(xi) and 1.2106(a) of the Commission's Rules and/or for Interim Conditional Waiver; Implementation of the Commercial Spectrum Enhancement Act and Modernization of the Commission's Competitive Bidding Rules and Procedures,* Report and Order, Order on Reconsideration of the First Report and Order, Third Order on Reconsideration of the Second Report and Order, and Third Report and Order, FCC 15–80, 30 FCC Rcd 7493 (2015), modified by *Erratum,* 30 FCC Rcd 8518 (2015) (*Part 1 R&O*)). Of relevance to the information collection at issue here, the Commission: (1) Implemented a new general prohibition on the filing of auction applications by entities controlled by the same individual or set of individuals (but with a limited exception for qualifying rural wireless partnerships); (2) modified the eligibility requirements for small business benefits, and updated the standardized schedule of small business sizes, including the gross revenues thresholds used to determine eligibility; (3) established a new bidding credit for eligible rural service providers; (4) adopted targeted attribution rules to prevent the unjust enrichment of ineligible entities; and (5) adopted rules prohibiting joint bidding arrangements with limited exceptions. The updated Part 1 rules apply to applicants seeking licenses and permits.

Additionally, on June 2, 2014, the Commission released the *Mobile Spectrum Holdings R&O,* in which the Commission updated its spectrum screen and established rules for its upcoming auctions of low-band spectrum. Of relevance to the information collection at issue here, the Commission stated that it could reserve spectrum in order to ensure against excessive concentration in holdings of below-1–GHz spectrum (*In the Matter of Policies Regarding Mobile Spectrum Holdings, Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* FCC 14–63, Report and Order, 29 FCC Rcd 6133, 6190, para. 135 (2014) (*Mobile Spectrum Holdings R&O*). *See also Application Procedures for Broadcast Incentive Auction Scheduled to Begin on March 29, 2016; Technical Formulas for Competitive Bidding,* Public Notice, 30 FCC Rcd 11034, Appendix 3 (WTB 2015); *Wireless Telecommunications Bureau Releases Updated List of Reserve-Eligible Nationwide Service Providers in each PEA for the Broadcast Incentive Auction,* Public Notice, AU No. 14–252 (WTB 2016).

The Commission also revised the currently approved collection of information under OMB Control Number 3060–0798 to permit the collection of the additional information for Commission licenses and permits, pursuant to the rules and information collection requirements adopted by the Commission in the *Part 1 R&O* and the *Mobile Spectrum Holdings R&O.* As part of the collection, the Commission is now approved for the information collection and recordkeeping requirements associated with 47 CFR 1.2110(j), 1.2112(b)(2)(iii), 1.2112(b)(2)(v), 1.2112(b)(2)(vii), and 1.2112(b)(2)(viii). Also, in certain circumstances, the Commission requires the applicant to provide copies of their agreements and/or submit exhibits.

In addition, the Commission is now approved for various other, non-substantive editorial/consistency edits and updates to FCC Form 601 that correct inconsistent capitalization of words and other typographical errors, and better align the text on the form with the text in the Commission rules both generally and in connection with recent non-substantive, organizational amendments to the Commission's rules.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–15819 Filed 7–1–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 578

[Docket No. NHTSA–2016–0075]

RIN 2127–AL73

Civil Penalties

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Interim final rule.

SUMMARY: This interim final rule updates the maximum civil penalty amounts for violations of statutes and regulations administered by NHTSA pursuant the Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015. This final rule also amends our regulations to reflect the new civil penalty amounts for violations of the National Traffic and Motor Vehicle Safety (the Safety Act) Act authorized by the Fixing America's Surface Transportation Act (FAST Act).

DATES: *Effective date:* This rule is effective August 4, 2016.

Petitions for reconsideration: Petitions for reconsideration of this final rule must be received not later than August 19, 2016.

ADDRESSES: Any petitions for reconsideration should refer to the docket number of this document and be submitted to: Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., West Building, Fourth Floor, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Thomas Healy, Office of Chief Counsel, NHTSA, telephone (202) 366–2992, facsimile (202) 366–3820, 1200 New Jersey Ave SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the Federal Civil Penalties Inflation Adjustment Act Improvement Act (the 2015 Act), Pub. L. 114–74, Section 701, was signed into law. The purpose of the 2015 Act is to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The 2015 Act requires agencies to make an initial catch up adjustment to the civil monetary penalties they administer through an interim final rule and then to make subsequent annual adjustments for inflation. The amount of increase of any adjustment to a civil penalty pursuant to the 2015 Act is limited to

150 percent of the current penalty. Agencies are required to issue the interim final rule with the initial catch up adjustment by July 1, 2016.

The method of calculating inflationary adjustments in the 2015 Act differs substantially from the methods used in past inflationary adjustment rulemakings conducted pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act), Pub. L. 101–410. Previously, adjustments to civil penalties were conducted under rules that required significant rounding of figures. For example, a penalty increase that was greater than $1,000, but less than or equal to $10,000, would be rounded to the nearest multiple of $1,000. While this allowed penalties to be kept at round numbers, it meant that penalties would often not be increased at all if the inflation factor was not large enough. Furthermore, increases to penalties were capped at 10 percent. Over time, this formula caused penalties to lose value relative to total inflation.

The 2015 Act has removed these rounding rules; now, penalties are simply rounded to the nearest $1. While this creates penalty values that are no longer round numbers, it does ensure that penalties will be increased each year to a figure commensurate with the actual calculated inflation. Furthermore, the 2015 Act "resets" the inflation calculations by excluding prior inflationary adjustments under the Inflation Adjustment Act, which contributed to a decline in the real value of penalty levels. To do this, the 2015 Act requires agencies to identify, for each penalty, the year and corresponding amount(s) for which the maximum penalty level or range of minimum and maximum penalties was established (*i.e.*, originally enacted by Congress) or last adjusted other than pursuant to the Inflation Adjustment Act.

The Director of the Office of Management and Budget (OMB) provided guidance to agencies in a February 24, 2016 memorandum on how to calculate the initial adjustment required by the 2015 Act.[1] The initial catch up adjustment is based on the change between the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October in the year the penalty amount was established or last adjusted by Congress and the October 2015 CPI–U. The February 24, 2016 memorandum contains a table with a multiplier for the change in CPI–U from the year the penalty was established or last adjusted to 2015. To arrive at the adjusted penalty the agency must multiply the penalty amount when it was established or last adjusted by Congress, excluding adjustments under the Inflation Adjustment Act, by the multiplier for the increase in CPI–U from the year the penalty was established or adjusted provided in the February 24, 2016 memorandum. The 2015 Act limits the initial inflationary adjustment to 150 percent of the current penalty. To determine whether the increase in the adjusted penalty is less than 150 percent, the agency must multiply the current penalty by 250 percent. The adjusted penalty is the lesser of either the adjusted penalty based on the multiplier for CPI–U in Table A of the February 24, 2016 memorandum or an amount equal to 250% of the current penalty. This interim final rule adjusts the civil penalties for violations of statutes and regulations that NHTSA administers consistent with the February 24, 2016 memorandum.

II. Inflationary Adjustments to Penalty Amounts in 49 CFR Part 578

Changes to Civil Penalties for School Bus Related Violations of the Safety Act (49 CFR 578.6(a)(2))

The maximum civil penalty for a single violation of 30112(a)(1) of Title 49 of the United States Code involving school buses or school bus equipment, or of the prohibition on school system purchases and leases of 15 passenger vans as specified in 30112(a)(2) of Title 49 of the United States Code was set at $10,000 when the penalty was established by the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), Pub. L. 109–59, 119 Stat. 1942, enacted in 2005. Applying the multiplier for the increase in CPI–U for 2005 in Table A of the February 24, 2016 memorandum (1.19397) results in an adjusted civil penalty of $11,940. The maximum civil penalty for a related series of violations of 30112(a)(1) and 30112(a)(2) was $15,000,000 when the penalty was established by SAFETEA–LU in 2005. Applying the multiplier for the increase in CPI–U for 2005 results in an adjusted maximum civil penalty of $17,909,550.

Changes to Civil Penalties for Filing False or Misleading Reports Under 49 U.S.C. 30165(a)(4)

The Moving Ahead for Progress in the 21st Century Act (MAP–21) of 2012, Pub. L. 112–141, established a maximum civil penalty for persons knowingly or willfully submitting materially false or misleading information to NHTSA after certifying that the information was accurate pursuant to 49 U.S.C. 30166(o) of $5,000 per day. Applying the multiplier for the increase in CPI–U for 2012 in Table A of the February 24, 2016 memorandum (1.02819) results in an adjusted civil penalty of $5,141. MAP–21 established a maximum civil penalty for a related series of daily violations of 49 U.S.C. 30166(o) of $1,000,000. Applying the multiplier for the increase in CPI–U for 2012 results in an adjusted civil penalty of $1,028,190 for a related series of daily violations of 49 U.S.C. 30166(o).

Change to Penalty for Violation of 49 U.S.C. Chapter 305 (49 CFR 578.6(b))

The Anti Car Theft Act of 1992, Pub. L. 102–519, 204, 106 Stat. 3393 (1992) established a civil penalty of $1,000 for each violation of the reporting requirements related to maintaining the Nation Motor Vehicle Title Information System. Applying the multiplier for the increase in CPI–U for 1992 in Table A of the February 24, 2016 memorandum (1.67728) results in an adjusted civil penalty of $1,677.

Change to Maximum Penalty Under 49 U.S.C. 32506(a) (49 CFR 578.6(c))

The Motor Vehicle Information and Cost Savings Act (Cost Savings Act), Pub. L. 92–513, 86 Stat. 953, (1972), established a civil penalty of $1,000 for each violation of a bumper standard established pursuant to the Cost Savings Act. Applying the multiplier for the increase in CPI–U for 1972 in Table A of the February 24, 2016 memorandum (5.62265) results in an adjusted civil penalty of $5,623. Since this would result in an increase to the current civil penalty of greater than 150 percent, the adjusted civil penalty is $2,750 (Current penalty $1,100 × 2.5).

The Cost Savings Act also established a maximum civil penalty of $800,000 for a related series of violations of the bumper standards established pursuant to the Act. Applying the multiplier for the increase in CPI–U for 1972 in Table A of the February 24, 2016 memorandum (5.62265) results in an adjusted civil penalty of $4,498,120. Since this would result in an increase to the current civil penalty of greater than 150 percent, the adjusted civil penalty is $3,062,500 (Current penalty $1,225,000 × 2.5).

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[1] Memorandum from the Director of OMB to Heads of Executive Departments and Agencies, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Feb. 24, 2016), *available at www.whitehouse.gov/sites/default/files/omb/memoranda/2016/m-16-06.pdf.*

Change to Penalties Under the Consumer Information Provisions (49 CFR 578.6(d)(1))

The Cost Savings Act established a civil penalty of $1,000 for each violation of 49 U.S.C. 32308(a) related to providing information on crashworthiness and damage susceptibility. Applying the multiplier for the increase in CPI–U for 1972 in Table A of the February 24, 2016 memorandum (5.62265) results in an adjusted civil penalty of $5,623. Since this would result in an increase to the current civil penalty of greater than 150 percent, the adjusted civil penalty is $2,750 (Current penalty $1,100 × 2.5). The Cost Savings established a maximum civil penalty of $400,000 for a series of related violations of 49 U.S.C. 32308(a). Applying the multiplier for the increase in CPI–U for 1972 in Table A of the February 24, 2016 memorandum (5.62265) results in an adjusted civil penalty of $2,249,060. Since this would result in an increase to the current civil penalty of greater than 150 percent, the adjusted civil penalty is $1,500,000 (Current penalty $600,000 × 2.5).

Change to Penalties Under the Tire Consumer Information Provisions (49 CFR 578.6(d)(2))

The Energy Independence and Security Act of 2007, Pub. L. 110–140, 121 Stat. 1507 (2007) established a civil penalty of $50,000 for each violation related to the tire information fuel efficiency information program under 49 U.S.C. 32304A. Applying the multiplier for the increase in CPI–U for 2007 in Table A of the February 24, 2016 memorandum (1.13833) results in an adjusted civil penalty of $56,917.

Change to Penalties Under the Country of Origin Content Labeling Provisions (49 CFR 578.6(d)(2))

The American Automobile Labeling Act, Pub L. 102–388, § 210, 106 Stat. 1556 (1992), established a civil penalty of $1,000 for willfully failing to affix, or failing to maintain, the label required by the Act. Applying the multiplier for the increase in CPI–U for 1992 in Table A of the February 24, 2016 memorandum (1.67728) results in an adjusted civil penalty of $1,677.

Change to Penalties Under the Odometer Tampering and Disclosure Provisions (49 CFR 578.6(f))

MAP–21 adjusted the civil penalty for each violation of 49 U.S.C. Chapter 327 or a regulation issued thereunder related to odometer tampering and disclosure to $10,000 per violation. Applying the multiplier for the increase in CPI–U for 2012 in Table A of the February 24, 2016 memorandum (1.02819) results in an adjusted civil penalty of $10,282. MAP–21 established a maximum civil penalty of $1,000,000 for a related series of violations of 49 U.S.C. Chapter 327 or a regulation issued thereunder. Applying the multiplier for the increase in CPI–U for 2012 results in an adjusted civil penalty of $1,028,190 for a related series of violations.

MAP–21 also adjusted the civil penalty for violations of 49 U.S.C. Chapter 327 or a regulation issued thereunder with intent to defraud to $10,000 per violation. Applying the multiplier for the increase in CPI–U for 2012 results in an adjusted civil penalty of $10,282.

Change to Penalties Under the Vehicle Theft Protection Provisions (49 CFR 578.6(g))

The Motor Vehicle Theft Law Enforcement Act of 1984 (Vehicle Theft Act), Public Law 98–547, § 608, 98 Stat. 2762 (1984), established a civil penalty of $1,000 for each violation of 49 U.S.C. 33114(a)(1)–(4). Applying the multiplier for the increase in CPI–U for 1984 in Table A of the February 24, 2016 memorandum (2.25867) results in an adjusted civil penalty of $2,259. The Vehicle Theft Act also established a maximum penalty of $250,000 for a related series of violations of 49 U.S.C. 33114(a)(1)–(4). Applying the multiplier for the increase in CPI–U for 1984 results in an adjusted civil penalty of $564,668.

The Anti Car Theft Act of 1992 established a civil penalty of $100,000 per day for violations of the Anti Car Theft Act related to operation of a chop shop. Applying the multiplier for the increase in CPI–U for 1992 in Table A of the February 24, 2016 memorandum (1.67728) results in an adjusted civil penalty of $167,728.

Change to Penalties Under the Automobile Fuel Economy Provisions (49 CFR 578.6(g))

The Energy Policy and Conservation Act (EPCA) of 1975, Public Law 94–163, § 508, 89 Stat. 912 (1975), established a civil penalty of $10,000 for each violation of 49 U.S.C. 32911(a). Applying the multiplier for the increase in CPI–U for 1975 in Table A of the February 24, 2016 memorandum (4.3322) results in an adjusted civil penalty of $43,322. Since this would result in an increase to the current civil penalty of greater than 150 percent, the adjusted civil penalty is $40,000 (Current penalty $16,000 × 2.5).

EPCA also established a civil penalty of $5 multiplied by each .1 of a mile a gallon by which the applicable average fuel economy standard under that section exceeds the average fuel economy for automobiles to which the standard applies manufactured by the manufacturer during the model year, multiplied by the number of those automobile and reduced by the credits available to the manufacturer. Applying the multiplier for the increase in CPI–U for 1975 results in an adjusted civil penalty of $22. Since this would result in an increase to the current civil penalty of greater than 150 percent, the adjusted civil penalty is $14 (Current penalty $5.50 × 2.5).

In 1978 Congress amended EPCA, Public Law 95–619, 402, 92 Stat. 3255 (Nov. 9, 1978) to allow the Secretary of Transportation to establish a new civil penalty for each .1 of a mile a gallon by which the applicable average fuel economy standard under EPCA exceeds the average fuel economy for automobiles to which the standard applies manufactured by the manufacturer during the model year. These amendments, which are codified in 49 U.S.C. 32912(c), state that the new civil penalty cannot be more than $10. Applying the multiplier for the increase in CPI–U for 1978 in Table A of the February 24, 2016 memorandum (3.54453) to the $10 maximum penalty the Secretary is permitted to establish under 49 U.S.C. 32912(c) results in an adjusted civil penalty of $35. Since this would result in an increase of greater than 150 percent, the adjusted maximum civil penalty that the Secretary is permitted to establish under 49 U.S.C. 32912(c) is $25 (Current maximum penalty $10 × 2.5). Because the new maximum penalty that the Secretary is permitted to establish under 49 U.S.C. 32912(c) is $25, the new adjusted civil penalty in 49 CFR 578.6(h)(2) of $14 does not exceed the maximum penalty that the Secretary is permitted to impose.

Change to Penalties Under the Medium and Heavy Duty Vehicle Fuel Efficiency Program (49 CFR 578.6(i))

In 2011, the agency established a maximum penalty of $37,500 per vehicle or engine for violations of 49 CFR 535. Applying the multiplier for the increase in CPI–U for 2011 in Table A of the February 24, 2016 memorandum (1.05042) results in an adjusted civil penalty of $39,391.

III. Codification of Increases to NHTSA's Civil Penalty Authority in the FAST Act

On December 4, 2015, the FAST Act, Public Law 114–94, was signed into law. Section 24110 of the FAST Act increased the maximum civil penalty that NHTSA may collect for each violation of the Safety Act under 49 U.S.C. 30165(a)(1) and 49 U.S.C. 30165(a)(3) to $21,000 per violation (previously $7,000) and the maximum amount of civil penalties that NHTSA can collect for a related series of violations to $105 million (previously $35 million). In order for these increases to become effective, the Secretary of Transportation was required to certify to Congress that NHTSA has issued the final rule required by Section 31203 of MAP–21. Section 31203 required NHTSA to provide an interpretation of civil penalty factors in 49 U.S.C. 30165 for NHTSA to consider in determining the amount of penalty or compromise for violations of the Safety Act. Pub. L. 112–141, § 31203, 126 Stat. 758 (2012). The increases in maximum civil penalties in Section 24110 of the FAST Act became effective the date of the Secretary's certification.

NHTSA issued the final rule required by Section 31203 of MAP–21 on February 24, 2016. On March 17, 2016, the Secretary certified to Congress by letter to the Chairman and Ranking Member of the Senate Committee on Commerce, Science, and Transportation, and to the Chairman and Ranking Member of the House Committee on Energy and Commerce that NHTSA had issued the Final Rule. On March 22, 2016, the Office of the Secretary of Transportation published a notice in the **Federal Register** notifying the public that the increase was in effect.[2] NHTSA is codifying these increases in this interm final rule.

IV. Public Comment

NHTSA is promulgating this interim final rule to ensure that the amount of civil penalties contained in 49 CFR 578.6 reflect the statutorily mandated ranges as adjusted for inflation. Pursuant to the 2015 Act, NHTSA is required to promulgate a "catch-up adjustment" through an interim final rule. Pursuant to the 2015 Act and 5 U.S.C. 553(b)(3)(B), NHTSA finds that good cause exists for immediate implementation of this interim final rule without prior notice and comment because it would be impracticable to delay publication of this rule for notice and comment and because public comment is unnecessary. By operation of the Act, NHTSA must publish the catch-up adjustment by July 1, 2016. Additionally, the 2015 Act provides a clear formula for adjustment of the civil penalties, leaving the agency little room for discretion. Furthermore, the increases in NHTSA's civil penalty authority authorized by the FAST Act are already in effect and the amendments merely update 49 CFR 578.6 to reflect the new statutory civil penalty. For these reasons, NHTSA finds that notice and comment would be impracticable and is unnecessary in this situation.

V. Rulemaking Analyses and Notices

Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866, Executive Order 13563, and the Department of Transportation's regulatory policies and procedures. This rulemaking document was not reviewed under Executive Order 12866 or Executive Order 13563. This action is limited to the adoption of adjustments of civil penalties under statutes that the agency enforces, and has been determined to be not "significant" under the Department of Transportation's regulatory policies and procedures and the policies of the Office of Management and Budget. Because this rulemaking does not change the number of entities that are subject to civil penalties, the impacts are limited. Furthermore, excluding the penalties in 49 CFR 578.6(h)(2) for violations of Corporate Average Fuel Economy standards, this final rule does not establish civil penalty amounts that NHTSA is required to seek.

We also do not expect the increase in the civil penalty amount in 49 CFR 578.6(h)(2) to be economically significant. Over the last five model years, NHTSA has collected an average of $20 million per model year in civil penalties under 49 CFR 578.6(h)(2). Therefore, increasing the current civil penalty amount by 150 percent would not result in an annual effect on the economy of $100 million or more.

Furthermore, NHTSA contends that the economic effects of increasing the civil penalty in 49 CFR 578.6(h)(2) are not directly proportional to the increase in the amount of civil penalty. Manufacturers could pursue several strategies to avoid liability for civil penalties under 49 CFR 578.6(h)(2), including purchasing offset credits from other manufacturers, production and marketing changes to influence the average fuel economy of vehicles produced by the manufacturer, and vehicle design changes intended to increase the vehicle's fuel economy. NHTSA contends that manufacturers will pursue the strategy, or mix on strategies, that results in the lowest overall cost to the manufacturer. For this reason the expected economic impacts of this rule can be expected to be lower than the amount of the increase to the civil penalty amount in 49 CFR 578.6(h)(2).

Regulatory Flexibility Act

We have also considered the impacts of this rule under the Regulatory Flexibility Act. I certify that this rule will not have a significant economic impact on a substantial number of small entities. The following provides the factual basis for this certification under 5 U.S.C. 605(b). The amendments almost entirely potentially affect manufacturers of motor vehicles and motor vehicle equipment.

The Small Business Administration's regulations define a small business in part as a business entity "which operates primarily within the United States." 13 CFR 121.105(a). SBA's size standards were previously organized according to Standard Industrial Classification ("SIC") Codes. SIC Code 336211 "Motor Vehicle Body Manufacturing" applied a small business size standard of 1,000 employees or fewer. SBA now uses size standards based on the North American Industry Classification System ("NAICS"), Subsector 336—Transportation Equipment Manufacturing, which provides a small business size standard of 1,000 employees or fewer for automobile manufacturing businesses. Other motor vehicle-related industries have lower size requirements that range between 500 and 750 employees.

For example, according to the SBA coding system, businesses that manufacture truck trailers, travel trailers/campers, carburetors, pistons, piston rings, valves, vehicular lighting equipment, motor vehicle seating/interior trim, and motor vehicle stamping qualify as small businesses if they employ 500 or fewer employees. Similarly, businesses that manufacture gasoline engines, engine parts, electrical and electronic equipment (non-vehicle lighting), motor vehicle steering/suspension components (excluding springs), motor vehicle brake systems, transmissions/power train parts, motor vehicle air-conditioning, and all other motor vehicle parts qualify as small businesses if they employ 750 or fewer employees. See *http://www.sba.gov/size/sizetable.pdf* for further details.

Many small businesses are subject to the penalty provisions of 49 U.S.C. Chapter 301 (Safety Act) and therefore may be affected by the adjustments made in this rulemaking. For example, based on comprehensive reporting pursuant to the early warning reporting (EWR) rule under the Safety Act, 49 CFR part 579, of the more than 60 light vehicle manufacturers reporting, over half are small businesses. Also, there are other, relatively low production vehicle manufacturers that are not subject to comprehensive EWR reporting. Furthermore, there are about 70 registered importers. Equipment manufacturers (including importers), entities selling motor vehicles and motor vehicle equipment, and motor vehicle repair businesses are also subject to penalties under 49 U.S.C. 30165.

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[2] 81 FR 15413.

As noted throughout this preamble, this rule will only increase the penalty amounts that the agency could obtain for violations covered by 49 CFR 578.6. Under the Safety Act, the penalty provision requires the agency to take into account the size of a business when determining the appropriate penalty in an individual case. See 49 U.S.C. 30165(b). The agency would also consider the size of a business under its civil penalty policy when determining the appropriate civil penalty amount. See 62 FR 37115 (July 10, 1997) (NHTSA's civil penalty policy under the Small Business Regulatory Enforcement Fairness Act ("SBREFA")). The penalty adjustments would not affect our civil penalty policy under SBREFA.

Since, this regulation does not establish a penalty amount that NHTSA is required to seek, except for civil penalties under 49 CFR 578.6(h)(2), this rule will not have a significant economic impact on small businesses. Furthermore, low volume manufacturers can petition for an exemption from the Corporate Average Fuel Economy standards under 49 CFR part 525. This will lessen the impacts of this rulemaking on small business by allowing them to avoid liability for penalties under 49 CFR 578.6(h)(2). Small organizations and governmental jurisdictions will not be significantly affected as the price of motor vehicles and equipment ought not change as the result of this rule.

Executive Order 13132 (Federalism)

Executive Order 13132 requires NHTSA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, the agency may not issue a regulation with Federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, the agency consults with State and local governments, or the agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The reason is that this rule will generally apply to motor vehicle and motor vehicle equipment manufacturers (including importers), entities that sell motor vehicles and equipment and motor vehicle repair businesses. Thus, the requirements of Section 6 of the Executive Order do not apply.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires agencies to prepare a written assessment of the cost, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually. Because this rule will not have a $100 million effect, no Unfunded Mandates assessment will be prepared.

Executive Order 12778 (Civil Justice Reform)

This rule does not have a retroactive or preemptive effect. Judicial review of this rule may be obtained pursuant to 5 U.S.C. 702. That section does not require that a petition for reconsideration be filed prior to seeking judicial review.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, we state that there are no requirements for information collection associated with this rulemaking action.

Privacy Act

Please note that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit *http://dms.dot.gov.*

List of Subjects in 49 CFR Part 578

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, Tires, Penalties.

In consideration of the foregoing, 49 CFR part 578 is amended as set forth below.

PART 578—CIVIL AND CRIMINAL PENALTIES

■ 1. The authority citation for 49 CFR part 578 is revised to read as follows:

Authority: Pub. L. 101–410, Pub. L. 104–134, Pub. L. 109–59, Pub. L. 114–74, Pub. L. 114–94, 49 U.S.C. 30165, 30170, 30505, 32308, 32309, 32507, 32709, 32710, 32902, 32912, and 33115; delegation of authority at 49 CFR 1.81, 1.95.

■ 2. Section 578.6 is revised to read as follows:

§ 578.6 Civil penalties for violations of specified provisions of Title 49 of the United States Code.

(a) *Motor vehicle safety*—(1) *In general.* A person who violates any of sections 30112, 30115, 30117 through 30122, 30123(a), 30125(c), 30127, or 30141 through 30147 of Title 49 of the United States Code or a regulation prescribed under any of those sections is liable to the United States Government for a civil penalty of not more than $21,000 for each violation. A separate violation occurs for each motor vehicle or item of motor vehicle equipment and for each failure or refusal to allow or perform an act required by any of those sections. The maximum civil penalty under this paragraph for a related series of violations is $105,000,000.

(2) *School buses.* Notwithstanding paragraph (a)(1) of this section, a person who:

(i) Violates section 30112(a)(1) of Title 49 United States Code by the manufacture, sale, offer for sale, introduction or delivery for introduction into interstate commerce, or importation of a school bus or school bus equipment (as those terms are defined in 49 U.S.C. 30125(a)); or

(ii) Violates section 30112(a)(2) of Title 49 United States Code, shall be subject to a civil penalty of not more than $11,940 for each violation. A separate violation occurs for each motor vehicle or item of motor vehicle equipment and for each failure or refusal to allow or perform an act required by this section. The maximum penalty under this paragraph for a related series of violations is $17,909,550.

(3) *Section 30166.* A person who violates section 30166 of Title 49 of the United States Code or a regulation prescribed under that section is liable to the United States Government for a civil penalty for failing or refusing to allow or perform an act required under that section or regulation. The maximum penalty under this paragraph is $21,000 per violation per day. The maximum penalty under this paragraph for a related series of daily violations is $105,000,000.

(4) *False and misleading reports.* A person who knowingly and willfully submits materially false or misleading information to the Secretary, after certifying the same information as accurate under the certification process established pursuant to section 30166(o), shall be subject to a civil penalty of not more than $5,141 per day. The maximum penalty under this paragraph for a related series of daily violations is $1,028,190.

(b) *National Automobile Title Information System.* An individual or entity violating 49 U.S.C. Chapter 305 is liable to the United States Government for a civil penalty of not more than $1,677 for each violation.

(c) *Bumper standards.* (1) A person that violates 49 U.S.C. 32506(a) is liable to the United States Government for a civil penalty of not more than $2,750 for each violation. A separate violation occurs for each passenger motor vehicle or item of passenger motor vehicle equipment involved in a violation of 49 U.S.C. 32506(a)(1) or (4)—

(i) That does not comply with a standard prescribed under 49 U.S.C. 32502, or

(ii) For which a certificate is not provided, or for which a false or misleading certificate is provided, under 49 U.S.C. 32504.

(2) The maximum civil penalty under this paragraph (c) for a related series of violations is $3,062,500.

(d) *Consumer information*—(1) *Crashworthiness and damage susceptibility.* A person who violates 49 U.S.C. 32308(a), regarding crashworthiness and damage susceptibility, is liable to the United States Government for a civil penalty of not more than $2,750 for each violation. Each failure to provide information or comply with a regulation in violation of 49 U.S.C. 32308(a) is a separate violation. The maximum penalty under this paragraph for a related series of violations is $1,500,000.

(2) *Consumer tire information.* Any person who fails to comply with the national tire fuel efficiency program under 49 U.S.C. 32304A is liable to the United States Government for a civil penalty of not more than $56,917 for each violation.

(e) *Country of origin content labeling.* A manufacturer of a passenger motor vehicle distributed in commerce for sale in the United States that willfully fails to attach the label required under 49 U.S.C. 32304 to a new passenger motor vehicle that the manufacturer manufactures or imports, or a dealer that fails to maintain that label as required under 49 U.S.C. 32304, is liable to the United States Government for a civil penalty of not more than $1,677 for each violation. Each failure to attach or maintain that label for each vehicle is a separate violation.

(f) *Odometer tampering and disclosure.* (1) A person that violates 49 U.S.C. Chapter 327 or a regulation prescribed or order issued thereunder is liable to the United States Government for a civil penalty of not more than $10,281 for each violation. A separate violation occurs for each motor vehicle or device involved in the violation. The maximum civil penalty under this paragraph for a related series of violations is $1,028,190.

(2) A person that violates 49 U.S.C. Chapter 327 or a regulation prescribed or order issued thereunder, with intent to defraud, is liable for three times the actual damages or $10,281, whichever is greater.

(g) *Vehicle theft protection.* (1) A person that violates 49 U.S.C. 33114(a)(1)-(4) is liable to the United States Government for a civil penalty of not more than $2,259 for each violation. The failure of more than one part of a single motor vehicle to conform to an applicable standard under 49 U.S.C. 33102 or 33103 is only a single violation. The maximum penalty under this paragraph for a related series of violations is $564,668.

(2) A person that violates 49 U.S.C. 33114(a)(5) is liable to the United States Government for a civil penalty of not more than $167,728 a day for each violation.

(h) *Automobile fuel economy.* (1) A person that violates 49 U.S.C. 32911(a) is liable to the United States Government for a civil penalty of not more than $40,000 for each violation. A separate violation occurs for each day the violation continues.

(2) Except as provided in 49 U.S.C. 32912(c), a manufacturer that violates a standard prescribed for a model year under 49 U.S.C. 32902 is liable to the United States Government for a civil penalty of $14 multiplied by each .1 of a mile a gallon by which the applicable average fuel economy standard under that section exceeds the average fuel economy—

(i) Calculated under 49 U.S.C. 32904(a)(1)(A) or (B) for automobiles to which the standard applies manufactured by the manufacturer during the model year;

(ii) Multiplied by the number of those automobiles; and

(iii) Reduced by the credits available to the manufacturer under 49 U.S.C. 32903 for the model year.

(i) *Medium- and heavy-duty vehicle fuel efficiency.* The maximum civil penalty for a violation of the fuel consumption standards of 49 CFR part 535 is not more than $39,391 per vehicle or engine. The maximum civil penalty for a related series of violations shall be determined by multiplying $39,391 times the vehicle or engine production volume for the model year in question within the regulatory averaging set.

Issued on: June 22, 2016.

Mark R. Rosekind,

Administrator.

[FR Doc. 2016–15800 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–59–P

Proposed Rules

Federal Register
Vol. 81, No. 128
Tuesday, July 5, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1232

RIN 2590–AA42

Incentive-Based Compensation Arrangements

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of Proposed Rulemaking and Request for Comment; Correction.

SUMMARY: This document corrects a typographical error to the "Dated:" line of the Federal Housing Finance Agency's (FHFA) signatory block of the Notice of Proposed Rulemaking and Request for Comment (Proposed Rule) issued jointly by the Office of the Comptroller of the Currency, Board of Governors of the Federal Reserve System, Federal Deposit Corporation, National Credit Union Administration, FHFA, and the U.S. Securities Exchange Commission. The Proposed Rule was published in the **Federal Register** on Friday, June 10, 2016 (FR Doc. 2016–11788; 81 FR 37669), and concerned Incentive-based Compensation Arrangements.

FOR FURTHER INFORMATION CONTACT: Mary Pat Fox, Manager, Executive Compensation Branch, (202) 649–3215; or Lindsay Simmons, Assistant General Counsel, (202) 649–3066, Federal Housing Finance Agency, 400 7th Street SW., Washington, DC 20219. The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

Need for Correction

In the **Federal Register** of Friday, June 10, 2016, FR Doc. 2016–11788, on page 37838, in the third column, the "Dated:" line of the Federal Housing Finance Agency signatory block is corrected to read as "April 26, 2016."

Dated: June 22, 2016.

Melvin L. Watt,

Director, Federal Housing Finance Agency.

[FR Doc. 2016–15596 Filed 7–1–16; 8:45 am]

BILLING CODE 8070–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 275

[Release No. IA–4439; File No. S7–13–16]

RIN 3235–AL62

Adviser Business Continuity and Transition Plans

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Securities and Exchange Commission ("Commission" or "SEC") is proposing a new rule and rule amendments under the Investment Advisers Act of 1940 ("Advisers Act"). The proposed rule would require SEC-registered investment advisers to adopt and implement written business continuity and transition plans reasonably designed to address operational and other risks related to a significant disruption in the investment adviser's operations. The proposal would also amend rule 204–2 under the Advisers Act to require SEC-registered investment advisers to make and keep all business continuity and transition plans that are currently in effect or at any time within the past five years were in effect.

DATES: Comments should be received on or before September 6, 2016.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number S7–13–16 on the subject line; or
- Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–13–16. This file number should be included on the subject line if email is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/proposed.shtml*). Comments are also available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the Commission's Web site. To ensure direct electronic receipt of such notifications, sign up through the "Stay Connected" option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Andrea Ottomanelli Magovern, Senior Counsel, Zeena Abdul-Rahman, Senior Counsel, John Foley, Senior Counsel, or Alpa Patel, Branch Chief, at (202) 551-6787 or *IArules@sec.gov*, Investment Adviser Rulemaking Office, Division of Investment Management, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: The Commission is proposing for public comment new rule 206(4)–4 [17 CFR 275. 206(4)–4] and amendments to rule 204–2 [17 CFR 275.204–2] under the Advisers Act [15 U.S.C. 80b].

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I. Adviser Business Continuity and Transition Plans

A. Introduction

Today, there are approximately 12,000 investment advisers registered with the Commission that collectively manage over $67 trillion in assets, an increase of over 140% in the past 10 years.[1] Advisers manage assets for, and provide investment advice to, a wide variety of clients, including individuals, charitable organizations, endowments, retirement plans, and various pooled investment vehicles such as mutual funds and private funds. Investors turn to advisers for a variety of services such as helping them to identify financial goals (including investing for a child's education or preparing for retirement), analyzing an existing financial portfolio, determining an appropriate asset allocation, and providing portfolio management or investment recommendations to help achieve financial goals. Advisers also play an important role in counseling and advising clients on complex financial instruments and investments, and in providing advice and guidance on weathering changing market conditions. The range of services provided by advisers, and the continued growth in the number of advisers and assets under management, reflect the critical role investment advisers play in our capital markets and the importance of the services they provide to approximately 30 million clients.[2]

Investment advisers today also participate in and are part of an increasingly complex financial services industry. Advisers are relying on technology to a greater extent, managing more complicated portfolios and strategies that often include complex investments, and are increasingly relying on the services of third parties such as custodians, brokers and dealers, pricing services, and technology vendors[3] that support their operations.[4]

Although the types of registered investment advisers and their business models may vary significantly, they generally share certain fundamental operational risks. Of particular concern to the Commission are those risks that may impact the ability of an adviser and its personnel to continue operations, provide services to clients and investors, or, in certain circumstances, transition the management of accounts to another adviser. Such operational risks include, but are not limited to, technological failures with respect to systems and processes (whether proprietary or provided by third-party vendors supporting the adviser's activities), and the loss of adviser or client data, personnel, or access to the adviser's physical location(s) and facilities.

Operational risks can arise from internal and external business continuity events. An internal event, such as a facility problem at an adviser's primary office location, or an external event, such as a weather-related emergency or cyber-attack, could impact an adviser's ongoing operations and its ability to provide client services. For example, both types of events could prevent advisory personnel from accessing the adviser's office or its systems or documents at a particular office location. Under these circumstances, an adviser and its personnel may be unable to provide services to the adviser's clients and continue its operations while affected by the disruption, which could result in client harm.[5] Similarly, operational risks can arise in the context of a transition event. If, for example, an adviser is winding down or ceasing operations during a time of stress, then an adviser's ability to safeguard client assets could be impacted.

We understand that many investment advisers, like other financial services firms, already have taken critical steps to address and mitigate the risks of business disruptions, regardless of the source, as a prudent business measure.[6] Industry participants have also stated that the highly competitive environment in which advisers operate encourages proper risk management and contributes to advisers' attentiveness to operational risks.[7] Advisers may recognize the

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[1] Based on data from the Commission's Investment Adviser Registration Depository ("IARD") as of January 4, 2016.

[2] *Id.*

[3] We use the terms "vendor" and "service provider" interchangeably throughout this release.

[4] There has been an increase in the diversity of investment portfolios, strategies, and securities types, the complexity of portfolio management and operations, and the interconnectedness and interdependencies of the financial industry. *See generally,* Global Association of Risk Professionals (GARP), Risk Principles for Asset Managers, Prepared by the GARP Buy Side Risk Managers Forum (Sept. 2015) ("Risk Principles for Asset Managers") at Section 5: Operational Risk Principles, *available at http://go.garp.org/l/39542/2015-09-30/315zdc/39542/90066/BSRMF_Risk_Principles_2015.pdf.*

[5] As discussed in Section I.B.1. of this release, if an adviser is unable to provide services to its clients, its clients' interests may be at risk. This risk could include the risk of loss if, for example, an adviser lacks the ability to make trades in a portfolio, is unable to receive or implement directions from clients, or if clients are unable to access their assets or accounts.

[6] *See infra* notes 26–27 and accompanying text (discussing compliance policies and procedures required by rule 206(4)–7 under the Advisers Act); *see also* Comment Letter of BlackRock, Inc. to the Financial Stability Oversight Council's ("FSOC") Notice Seeking Comment on Asset Management Products and Activities ("FSOC Notice") (Mar. 25, 2015) ("BlackRock FSOC Comment Letter") at 10 ("In the normal course of business, asset managers implement measures to mitigate the impact of potentially disruptive events through operational risk management programs, including maintaining business continuity plans . . . and technology disaster recovery plans . . . ."); Comment Letter of Investment Company Institute to FSOC Notice (Mar. 25, 2015) ("ICI FSOC Comment Letter") at 69 (noting that "funds and key service providers to the industry have robust plans and strategies in place to facilitate the continuation or resumption of business operations in the event of an emergency, regardless of the cause"); Comment Letter of Vanguard to FSOC Notice (Mar. 25, 2015) ("Vanguard FSOC Comment Letter") at 23 ("The purpose of business continuity plans is to develop alternative ways to carry out normal business functions without access to facilities, systems, and/or key third-party providers of goods or services to the funds or its adviser.").

[7] *See, e.g.,* Comment Letter of Fidelity Investments to FSOC Notice (Mar. 25, 2015) ("Fidelity FSOC Comment Letter") at 22 ("It is not correct to imply that competitive pressures push managers toward less risk management; in fact those pressures push funds to improve their risk management practices."); BlackRock FSOC Comment Letter at 63 ("The asset management industry is highly competitive and there are numerous competitors across asset classes and investment strategies."); ICI FSOC Comment Letter

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potential for significant reputational damage and other costs associated with such risks.[8] For many advisers, the management of operational risks is part of the normal course of business to mitigate issues that could negatively impact client relationships and the management of client assets (including potential losses).[9] Deterioration in client relationships or financial losses could cause clients to move their accounts to another adviser or other financial services firm, and if done on a large scale, prompt the adviser to transition its business through a sale or other means or to wind down its operations and exit the market.

While we understand that many investment advisers already have taken steps to address and mitigate the risks of business disruptions,[10] our staff has observed a wide range of practices by advisers in addressing operational risk management. The staff frequently observes advisers managing operational and other risks through internal practices, procedures, and controls that are typically assessed by the adviser's legal, compliance, or audit staff, and often sees independent third-party assessments performed by audit or compliance firms.[11] However, the staff also has observed advisers with less robust planning, causing them to experience interruptions in their key business operations and inconsistently maintain communications with clients and employees during periods of stress.[12] As discussed further below, our staff has noted weaknesses in some adviser BCPs with respect to consideration of widespread disruptions, alternate locations, vendor relationships, telecommunications and technology, communications plans, and review and testing.[13] Although disparate practices may exist in light of the varying size and complexity of registrants, to effectively mitigate such risks we are proposing to require all SEC-registered investment advisers to have plans that are reasonably designed to address operational and other risks related to a significant disruption in the investment adviser's operations.

As described in more detail below, we are concerned about the adequacy of some advisers' plans to address operational and other risks associated with business resiliency. Our experience indicates that clients of advisers who do not have robust plans in place to address the operational and other risks related to significant disruptions in their operations are at greater risk of harm during such a disruption than the clients of advisers who do have such plans in place. As fiduciaries, investment advisers owe their clients a duty of care and a duty of loyalty, requiring them to put their clients' interests above their own.[14] As part of their fiduciary duty, advisers are obligated to take steps to protect client interests from being placed at risk as a result of the adviser's inability to provide advisory services.[15]

Section 206(4) of the Advisers Act authorizes the Commission to adopt rules and regulations that "define, and prescribe means reasonably designed to prevent, such acts, practices, and courses of business as are fraudulent, deceptive, or manipulative." Because an adviser's fiduciary duty obligates it to take steps to protect client interests from being placed at risk as a result of the adviser's inability to provide advisory services, clients are entitled to assume that advisers have taken the steps necessary to protect those interests in times of stress, whether that stress is specific to the adviser or the result of broader market and industry events. We believe it would be fraudulent and deceptive for an adviser to hold itself out as providing advisory services unless it has taken steps to protect clients' interests from being placed at risk as a result of the adviser's inability (whether temporary or permanent) to provide those services.

Accordingly, we believe advisers should be required to establish strong operational policies and procedures that manage the risks associated with business continuity and transitions. These policies and procedures should increase the likelihood that advisers are as prepared as possible to continue operations during times of stress and that they have taken steps to minimize risks that could lead to disruptions in their operations. These policies and procedures also should increase the likelihood that clients are not harmed in the event of a significant disruption in their adviser's operations. Therefore, today we are proposing to require SEC-registered advisers to adopt and implement written business continuity and transition plans that include certain specific components, and to maintain relevant records of those plans, in order to facilitate robust business continuity and transition planning across all SEC-registered advisers.

B. Background

1. Business Continuity Planning

The rapid recovery and resumption of the financial markets and the activities that support them underpins the resiliency of the U.S. financial system.[16]

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at 61 ("Regulated fund investors have considerable choice. The industry is highly competitive, with up to several hundred funds available within each investment category. Along with investment performance, the quality of shareholder services is a highly important factor in attracting and retaining fund investors.").

[8] *See, e.g.,* BlackRock FSOC Comment Letter at 55 ("Issues related to operational and business continuity risk can be costly and/or harm an asset manager's reputation with its clients."); Comment Letter of Managed Funds Association to FSOC Notice (Mar. 25, 2015) ("MFA FSOC Comment Letter") at 45 ("It is in every manager's self-interest to have appropriate plans in place to handle emergencies.").

[9] *See, e.g.,* BlackRock FSOC Comment Letter at 10 ("In the normal course of business, asset managers implement measures to mitigate the impact of potentially disruptive events through operational risk management programs, including maintaining business continuity plans . . . ."); Fidelity FSOC Comment Letter at 32 ("Fidelity devotes significant time and resources to ensuring that we can provide the services our clients expect even in exigent circumstances.").

[10] *See, e.g.,* Comment Letter of Securities Industry and Financial Markets Association and the Investment Adviser Association to FSOC Notice (Mar. 25, 2015) ("SIMFA/IAA FSOC Comment Letter") at 43 ("Of potentially more significant interest, asset managers are keenly focused on business continuity planning, disaster recovery, data protection, and cybersecurity issues—not just because of regulatory requirements . . . but also as a business imperative.").

[11] We recognize that some asset management firms have well-established sophisticated enterprise risk management ("ERM") practices built upon widely followed frameworks. *See, e.g.,* SIMFA/IAA FSOC Comment Letter at 42–43. The letter notes that in larger more sophisticated asset managers, operational risks can be addressed by an ERM framework such as the Committee of Sponsoring Organizations ("COSO") framework that works to identify key risk elements within the firm and how those elements are monitored and risks mitigated. *See* COSO, Enterprise Risk Management—Integrated Framework (Sept. 2004), *available at http://www.coso.org/Publications/ERM/COSO_ERM_ExecutiveSummary.pdf.* We understand that investment advisers with ERM programs typically consider business continuity as part of their broader management of operational risks. Accordingly, we believe that an adviser's business continuity and transition plan under the proposed rule could be a part of the adviser's existing ERM program.

[12] *See* NEP Risk Alert, *infra* note 30, at 3.

[13] *See* NEP Risk Alert, *infra* note 30; *see also infra* notes 31–35 and accompanying text.

[14] *See* SEC v. Capital Gains Research Bureau, Inc., 375 U.S. 180, 191, 194 (1963) (noting that the Advisers Act "reflects a congressional recognition 'of the delicate fiduciary nature of an investment advisory relationship'" and stating that "[c]ourts have imposed on a fiduciary an affirmative duty of 'utmost good faith, and full and fair disclosure of all material facts,' as well as an affirmative obligation 'to employ reasonable care to avoid misleading' his clients" (citations omitted)); Transamerica Mortgage Advisors, Inc. v. Lewis, 444 U.S. 11, 17 (1979) (noting that the Advisers Act's "legislative history leaves no doubt that Congress intended to impose enforceable fiduciary obligations").

[15] *See* Compliance Programs of Investment Companies and Investment Advisers, Advisers Act Rel. No. 2204 (Dec. 17, 2003) [68 FR 74714 (Dec. 24, 2003)] ("Compliance Program Adopting Release") at n.22 (noting this fiduciary obligation in the context of BCPs).

[16] *See* Interagency Paper on Sound Practices to Strengthen the Resilience of the U.S. Financial System, Securities Exchange Act Rel. No. 47638

Business continuity planning is a critical activity that supports resiliency and one that financial services firms, including investment advisers, generally should engage in to address the inherent risks they face in serving their clients' needs. Federal and state financial market and services regulators, including the Commission, have sought to highlight and address operational risks and the tools necessary to manage them, including fulsome business continuity planning for many financial industry participants.[17]

For example, the Financial Industry Regulatory Authority ("FINRA") requires broker-dealers to establish business continuity plans ("BCPs") reasonably designed to meet existing customer obligations and address relationships with other broker-dealers and counterparties.[18] Additionally, the Commodity Futures Trading Commission ("CFTC") has adopted regulations that require swap dealers and major swap participants to establish and maintain BCPs that are designed to enable the regulated entity "to continue or to resume any operations by the next business day with minimal disturbance to its counterparties and the market."[19] The North American Securities Administrator Association ("NASAA") also recently adopted a model rule that, if adopted in a particular state, would require investment advisers registered in that state to have business continuity and succession plans in place that minimize "service disruptions and client harm that could result from a sudden significant business disruption."[20]

In addition, we recently adopted rules to strengthen the technology infrastructure of the U.S. securities markets by adopting Regulation Systems Compliance and Integrity, or Regulation SCI, which applies to, among other things, self-regulatory organizations, certain alternative trading systems, and certain exempt clearing agencies.[21] Specifically, Regulation SCI is designed to reduce the occurrence of systems issues and improve resiliency for key market participants when these problems do occur, and requires, among other things, relevant entities to have and test business continuity and disaster recovery plans. While these regulations and those of other regulatory bodies address different entities, they generally highlight similar principles of business continuity planning, including the need to address critical systems, data backup, communications, alternate and/or geographically diverse locations, and third-party relationships.

Regulatory authorities have also acted collectively and in consultation with each other to address operational risks in light of the interconnectedness and interdependency of financial market participants. For example, the Commission, along with the Board of Governors of the Federal Reserve System ("Federal Reserve") and the Office of the Comptroller of the Currency, issued the Interagency Paper on Sound Practices to Strengthen the Resilience of the Financial System, which sets forth business continuity objectives for all financial firms and the U.S. financial system as a whole.[22] More recently, FSOC issued a request for public comment on, among other things, operational risks and transition planning as it relates to the asset management industry.[23]

(Apr. 7, 2003) [68 FR 17809 (Apr. 11, 2003)] ("Interagency Paper"); *cf. infra* note 21 and accompanying text.

[17] *See* Regulation Systems Compliance and Integrity, Securities Exchange Act Rel. No. 73639 (Nov. 19, 2014) [79 FR 72251 (Dec. 5, 2014)] ("Regulation SCI Adopting Release"); *see also* Policy Statement: Business Continuity Planning for Trading Markets, Securities Exchange Act Rel. No. 48545 (Sept. 25, 2003). In addition, we note that banks are subject to the Federal Financial Institutions Examination Council's ("FFIEC") business continuity guidelines, which state that financial institutions should develop comprehensive BCPs and that "[t]he goal of the BCP should be to minimize financial losses to the institution, serve customers and financial markets with minimal disruptions, and mitigate the negative effects of disruptions on business operations." *See* FFIEC, IT Examination Handbook, Business Continuity Planning (Feb. 2015) ("FFIEC Handbook"), *available at http://ithandbook.ffiec.gov/ITBooklets/FFIEC_ITBooklet_BusinessContinuityPlanning.pdf*; *see also* Board of Governors of the Federal Reserve System, Supervisory Letter SR 15–3 (Feb. 6, 2015), *available at http://www.federalreserve.gov/bankinforeg/srletters/sr1503.htm*. The FFIEC is an "interagency body empowered to prescribe uniform principles, standards, and report forms for the federal examination of financial institutions by the Board of Governors of the Federal Reserve System (FRB), the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), the Office of the Comptroller of the Currency (OCC), and the Consumer Financial Protection Bureau (CFPB)." *See* FFIEC, *available at https://www.ffiec.gov*.

[18] *See* FINRA Rule 4370 (requiring that member BCPs address certain elements, including data backup and recovery, all mission critical systems, alternate communications, alternate physical location of employees, and critical business constituent (*i.e.*, a business with which a member firm has an ongoing commercial relationship in support of the member's operating activities), bank and counter-party impact); *see also* NASD, Notice to Members 04–37: Business Continuity Plans (May 2004), *available at https://www.finra.org/sites/default/files/NoticeDocument/p003095.pdf*. We note that investment advisers that are also registered as broker-dealers would have to comply with FINRA's rule as well as the proposed rule. However, as noted herein, we have modeled much of the proposed rule, including the required components of a business continuity and transition plan, on BCP requirements for other financial services firms that we believe share similar vulnerabilities as investment advisers. *See infra* notes 61–62 and accompanying text.

[19] *See* 17 CFR 23.603(a). Relevant BCPs must be designed to recover all documentation and data required to be maintained by applicable law and regulation, and are required to include certain required components that are related to, among other things, data backup, systems maintenance, communications, geographic diversity, and third parties. *See infra* notes 62, 71, 79, and 86.

[20] *See* NASAA Model Rule 203(a)–1A (stating that all plans should provide for backup of books and records, alternate means of communication, office relocations, assignment of duties to qualified persons in the event of death or unavailability of key personnel, and otherwise minimizing service disruption and client harm); *see also* Mark Schoeff Jr., *State Regulators to Require Continuity Plans,* Investment News, (Apr. 22, 2015), *available at http://www.investmentnews.com/article/20150422/FREE/150429965/state-regulators-to-require-continuity-plans.*

[21] *See* Regulation SCI Adopting Release, *supra* note 17. Among other things, Regulation SCI requires SCI entities to establish and test business continuity and disaster recovery plans that include maintaining backup and recovery capabilities sufficiently resilient and geographically diverse and that are reasonably designed to achieve next business day resumption of trading and two-hour resumption of critical systems in the event of a wide-scale disruption. *See* 17 CFR 242.1001(a)(2)(v). Further, Regulation SCI sets forth business continuity and disaster recovery plan testing requirements for SCI entities. *See* 17 CFR 242.1004.

[22] *See* Interagency Paper, *supra* note 16. The objectives discussed in the paper include (i) rapid recovery and timely resumption of critical operations following a wide-scale disruption; (ii) rapid recovery and timely resumption of critical operations following the loss or inaccessibility of staff in at least one major operating location; and (iii) a high level of confidence, through ongoing use or robust testing, that critical internal and external continuity arrangements are effective and compatible. The paper also sets forth four sound practices for core clearing and settlement organizations and firms that play significant roles in critical financial markets, including (i) identifying clearing and settlement activities in support of critical financial markets, (ii) determining appropriate recovery and resumption objectives, (iii) maintaining sufficient geographically dispersed resources to meet such objectives, and (iv) routinely using or testing recovery and resumption arrangements. *See id.* In addition, in 2012–2013, the Commission's Office of Compliance Inspections and Examinations ("OCIE"), along with FINRA and the CFTC, jointly reviewed a number of firms' business continuity and disaster recovery planning and published their joint observations on best practices and lessons learned. *See* Joint Review of Business Continuity and Disaster Recovery of Firms by the Commission's National Examination Program, CFTC's Division of Swap Dealers and Intermediary Oversight and FINRA (Aug. 16, 2013) *("Joint Review of Business Continuity"), available at https://www.sec.gov/about/offices/ocie/jointobservations-bcps08072013.pdf.*

Financial services industry participants have also been pro-active in addressing resiliency issues. *See, e.g.*, Financial Services Sector Coordinating Council (established to coordinate infrastructure and homeland security activities within the financial services industry comprised on financial trade associations, financial utilities and financial firms), *available at https://www.fsscc.org.*

[23] *See* FSOC Notice (Dec. 24, 2014) [79 FR 77488 (Dec. 24, 2014)], *available at http://www.treasury.gov/initiatives/fsoc/rulemaking/Documents/Notice%20Seeking%20Comment%20on%20Asset%20Management%20Products%20and%20*

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The Commission addressed business continuity planning with respect to investment advisers in a general way when it adopted rule 206(4)–7 under the Advisers Act (“Compliance Program Rule”). Under the rule, advisers are required to consider their fiduciary and regulatory obligations under the Advisers Act, and adopt and implement written compliance policies and procedures reasonably designed to prevent violations of the Advisers Act.[24] At the time it adopted the rule, the Commission was concerned that not all advisers had adopted adequate compliance programs and as a result, clients and investors were being harmed.[25] In the release adopting the Compliance Program Rule, the Commission stated that an adviser's compliance policies and procedures should address BCPs to the extent that they are relevant to an adviser.[26] The Commission did not, however, identify critical components of a BCP or discuss specific issues or areas that advisers should consider in developing such plans.

As discussed above, an adviser's fiduciary obligations require it to take steps to protect its clients' interests from being placed at risk as a result of the adviser's inability to provide advisory services.[27] This fiduciary duty fosters trust between the client and its adviser, such that the client relies on the adviser to act in its best interests and safeguard its assets as appropriate, even during times of stress.[28] If an adviser is unable to provide advisory services after, for example, a natural disaster, a cyber-attack, an act of terrorism, technology failures, or the departure of key personnel, its temporary inability to continue operations may put clients' interests at risk and prevent it from meeting its fiduciary duty to clients. This risk could include the risk of loss if, for example, an adviser lacks the ability to make trades in a portfolio, is unable to receive or implement directions from clients, or if clients are unable to access their assets or accounts. As part of its fiduciary duty to protect client interests, an adviser also should take steps to minimize operational and other risks that could lead to a significant business disruption like, for example, a systems failure. In order to do so, advisers should generally assess and inventory the components of their business and minimize the scope of its vulnerability to a significant business disruption. While we recognize that an adviser may not be able to prevent significant business disruptions (*e.g.*, a natural disaster, terrorist attack, loss of service from a third-party), we believe robust planning for significant business disruptions can help to mitigate their effects and, in some cases, minimize the likelihood of their occurrence.

Various weather-related events have tested, on a large scale, the effectiveness of existing BCP components of advisers' compliance programs.[29] In addition, these events provided our examination staff the opportunity to review, observe, and assess the operations and resiliency of BCPs across many advisers. The examination staff followed these reviews by issuing public reports of their findings and effective practices.[30]

Hurricane Sandy broadly impacted the industry and its operations because of the duration and point of impact of the storm, which affected parts of New York, New Jersey, and the surrounding areas, where numerous financial services providers (both markets and participants) are concentrated. In the aftermath of the hurricane, examiners observed that the degree of specificity of advisers' written BCPs varied and that some advisers' BCPs did not “adequately address and anticipate widespread events.” [31] In addition, with respect to alternative locations, examination staff noted that some advisers did not have geographically diverse office locations, even when they recognized that diversification would be appropriate.[32] Additionally, they observed with respect to vendor relationships and telecommunications/technology, that certain advisers did not evaluate the BCPs of their service providers or engage service providers to ensure their backup servers worked properly, and that some advisers reported that they did not keep updated lists of their vendors and respective contacts.[33] Moreover, with respect to communications plans, the examination staff observed that some advisers inconsistently planned how to contact and deploy employees during a crisis, inconsistently maintained communications with clients and employees, and did not identify which personnel were responsible for executing and implementing the various portions of the BCP.[34] Finally, with respect to review and testing, our examination staff reported that some advisers “inadequately tested their BCPs relative to their advisory businesses.” [35] These observations illustrate our experience that business continuity planning among investment advisers

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Activities.pdf; see also FSOC, Update on Review of Asset Management Products and Activities (Apr. 18, 2016), *available at https://www.treasury.gov/initiatives/fsoc/news/Documents/FSOC%20Update%20on%20Review%20of%20Asset%20Management%20Products%20and%20Activities.pdf.* Although our rulemaking proposal is independent of FSOC, several commenters responding to the FSOC Notice discussed operational risks and transition issues related to investment advisers, and we have considered and discussed relevant comments throughout this release. Comments submitted in response to the FSOC Notice are available at *https://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=FSOC-2014-0001.*

[24] *See* rule 206(4)–7; Compliance Program Adopting Release, *supra* note 15, at section II.A.1. Rule 206(4)–7 makes it unlawful for advisers to provide investment advice unless they adopt and implement written compliance policies and procedures reasonably designed to prevent violations by the adviser and its supervised persons of the Advisers Act and rules thereunder.

[25] The Commission noted that it and state securities authorities had recently discovered unlawful conduct involving a number of advisers, broker-dealers, and other service providers where personnel of these entities engaged in, or actively assisted others in engaging in, inappropriate market timing, late trading of fund shares, and the misuse of material, nonpublic information about fund portfolios. The Commission noted that these personnel had breached their fiduciary obligations to the funds involved and their shareholders by placing their own interests or the interests of the fund adviser ahead of the interests of fund shareholders. *See* Compliance Program Adopting Release, *supra* note 15, at section I.

[26] *Id.* The Commission identified ten areas adviser compliance programs should address, including BCPs.

[27] *See id.* at n.22. The Commission also has stated that “clients of an adviser that is engaged in the active management of their assets would ordinarily be placed at risk if the adviser ceased operations.” *Id.*

[28] *See generally* SEC v. Capital Gains Research Bureau, Inc., *supra* note 14 at 191 (“A fiduciary owes its clients more than mere honesty and good faith alone. ”); Investment Adviser Association, What is an Investment Adviser?, *available at http://www.investmentadviser.org/eweb/dynamicpage.aspx?webcode=whatisia* (noting that because advisers owe a fiduciary duty to their clients, they “[stand] in a special relationship of trust and confidence with [their] clients” and that such fiduciary duty generally includes the duty to place the clients' interests first “at all times”).

[29] For example, Hurricane Katrina in 2005 and, as discussed in this release, Hurricane Sandy in 2012 presented challenges to advisers affected by those storms.

[30] *See* National Exam Program Risk Alert, SEC Examinations of Business Continuity Plans of Certain Advisers Following Operational Disruptions Caused by Weather-Related Events Last Year (Aug. 27, 2013) (“NEP Risk Alert”), *available at https://www.sec.gov/about/offices/ocie/business-continuity-plans-risk-alert.pdf.* The examination was part of a joint review by the SEC's OCIE, FINRA and the CFTC of relevant firms' business continuity and disaster recovery planning in the wake of Hurricane Sandy. Together, these entities issued a joint statement setting forth best practices and lessons learned as a result of their review. *See* Joint Review of Business Continuity, *supra* note 22; *see also* SEC Compliance Alert (June 2007) (“Compliance Alert”), *available at https://www.sec.gov/about/offices/ocie/complialert.htm.*

[31] *See* NEP Risk Alert, *supra* note 30, at 3.

[32] *See* NEP Risk Alert, *supra* note 30, at 4.

[33] *See* NEP Risk Alert, *supra* note 30, at 4–5.

[34] *See* NEP Risk Alert, *supra* note 30, at 6.

[35] *See* NEP Risk Alert, *supra* note 30, at 7.

can be uneven and, in some instances, may not be sufficiently robust to mitigate the potential adverse effects of a significant business disruption on clients.

Additionally, the operational complexity of advisers has increased over the years and many advisers' operations are highly dependent on technology, including investment processes (*e.g.*, trading, risk management operations) and client services.[36] It is critical for investment advisers to focus on resiliency so that they can continue to provide services to their clients when events impact the availability of systems, facilities, and staff. The ability to recover such systems, including third-party vendor provided platforms and services, and business operations in a timeframe that meets business requirements is important to mitigating the consequences of disruptive events.[37]

Based on the staff's observations from examinations, and the ever-growing complexity of, and risks to, operations, we are concerned that some advisers may not have robust BCPs. When a client entrusts an adviser to manage its assets, the client does so with the expectation that the adviser will act in its best interests and safeguard its assets as appropriate, even in times of stress. We believe that without robust business continuity planning, an adviser's clients may be placed at risk in times of stress. Accordingly, to facilitate such robust planning across all SEC-registered advisers, we are proposing to require that these advisers address certain components in their business continuity and transition plans.

2. Transition Planning

Operational risks are not limited to affecting the day-to-day operations of an adviser, but can lead to a financial services firm having to cease or wind-down operations while also considering how to safeguard client or investor assets. The 2008 financial crisis demonstrated that providers of financial services are at risk of having to exit the market unexpectedly and having to do so quickly.[38] As with traditional business continuity planning, regardless of whether the risk is internal or external to the firm, a reasonably designed plan assessing various risks related to a business transition (*e.g.*, operational and other risks related to transitioning client assets) and how to react to transition events should ameliorate the impact of transitions on clients.[39] After the financial crisis, Congress addressed the need for this type of advance planning for certain institutions in the Dodd-Frank Wall Street Reform and Consumer Protection Act, which mandated regulations that require certain financial institutions to plan for "rapid and orderly resolution in the event of material financial distress or failure."[40]

In the normal course of business, it is our understanding that advisers routinely transition client accounts without a significant impact to themselves, their clients, or the financial markets.[41] We believe that much of this is largely attributable to the agency relationship of advisers managing the assets on behalf of their clients and the regulatory framework supporting this relationship whereby advisory client assets for which the adviser has custody are required to be held at a qualified custodian, such as a bank or broker-dealer.[42] Because client assets custodied by an adviser must be held at a qualified custodian and segregated from the adviser's assets, we have observed that transitioning accounts from one adviser to another can largely be a streamlined process that in many cases may not involve the physical movement or sale of assets.[43] Pooled investment vehicle clients generally have the ability to terminate the advisory contract of the adviser or remove the governing body that may provide advisory services (*e.g.*, general partner or managing member) and appoint a new adviser or governing body if they so desire, while separate account clients can generally terminate the advisory contract and appoint a new adviser to manage their assets, all while their assets are typically maintained at a qualified custodian.[44]

In addition, we are aware of instances of non-routine disruptions at large advisory businesses that have resulted in transitions to new advisers or new ownership without appearing to have a significant adverse impact on clients, fund investors, or the financial markets.[45] Advisers routinely enter and exit the market and are capable of transferring client assets to another adviser or distributing such assets back to the client without negatively impacting the client.[46] Cases of advisory firms experiencing transition events are often caused by a rapid decrease in assets under management, which can occur for a variety of reasons, including poor performance or an event causing reputational harm.[47] To help ensure that a transition is as seamless as possible, an adviser must be aware of the impediments that should be addressed to minimize potential client impact.

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[36] *See, e.g.*, Blackrock, The Role of Technology Within Asset Management (Aug. 2014), at 1, *available at http://www.blackrock.com/corporate/en-us/literature/whitepaper/viewpoint-asset-management-technology-aug-2014.pdf* ("Asset managers require systems to facilitate the maintenance of data and flow of information in the investment process, such as trading counterparties and custodians. Technology provides the unseen 'plumbing' that ensures information flows smoothly throughout the ecosystem."). The paper also notes that a robust asset management process requires both experienced professionals and technology, and that integrated investment technology enhances the quality of large volumes of data, supports consistent investment workflows and enables timely communications for both internal functions and with external parties.

[37] *See, e.g., infra* note 90.

[38] *See* Financial Crisis Inquiry Commission, Final Report of the National Commission on the Causes of the Financial and Economic Crisis in the United States (Jan. 2011) at 22–23, *available at https://www.gpo.gov/fdsys/pkg/GPO-FCIC/pdf/GPO-FCIC.pdf* ("In January 2008, Bank of America announced it would acquire the ailing lender Countrywide. . . . Bear Stearns . . . was bought by JP Morgan with government assistance in the spring. Before the summer was over, Fannie Mae and Freddie Mac would be put into conservatorship. Then, in September, Lehman Brothers failed and the remaining investment banks, Merrill Lynch, Goldman Sachs, and Morgan Stanley, struggled as they lost the market's confidence. AIG . . . was rescued by the government. Finally, many commercial banks and thrifts . . . teetered. IndyMac had already failed over the summer; in September, Washington Mutual became the largest bank failure in U.S. history. In October, Wachovia struck a deal to be acquired by Wells Fargo."). Several of the financial services firms mentioned in this report included asset management subsidiaries.

[39] Both transition planning and business continuity planning relate to instances where an adviser may be unable to provide advisory services and where advance planning for those instances would benefit advisers and their clients. We note that in the Compliance Program Adopting Release, the Commission noted the risks to advisory clients if an adviser ceased operations. *See* Compliance Program Adopting Release, *supra* note 15.

[40] *See* section 165(d) of the Dodd-Frank Act [12 U.S.C. 5365]; *see also* Resolution Plans Required, 76 FR 67323 (Nov. 1, 2011) ("Resolution Plans"). We are not proposing that advisers adopt resolution plans or "living wills" similar to that which certain financial institutions must now adopt under FDIC and Federal Reserve rules because investment advisers do not interact with the government in the same way as banks. For example, advisers do not accept insured "deposits," do not have access to the Federal Reserve discount window, and do not use their own balance sheets when trading client assets.

[41] *See, e.g.*, BlackRock FSOC Comment Letter (noting that "[t]ransitioning the management of client assets from one manager to another regularly occurs in the normal course of business" and listing 19 previous examples of advisers or funds exiting the market without great market impact); SIMFA/IAA FSOC Comment Letter (noting that "managers and funds routinely enter and exit the asset management industry" and citing an Investment Company Institute paper to note that, in 2013, "48 mutual fund sponsors left the business without any impact or distress"); Comment Letter of PIMCO to FSOC Notice (Mar. 25, 2015); Vanguard FSOC Comment Letter. In addition, we understand that specialized transition managers exist to manage assets during a transition from one adviser to another. *See, e.g.*, BlackRock FSOC Comment Letter at 66.

[42] *See* rule 206(4)–2 under the Advisers Act. The use of custodians that traditionally provide those services provide protection for client assets from the adverse effects of stress at an adviser. We also note that approximately 96.7% of SEC-registered advisers are not related to the custodians that hold client assets. Based on data from the Commission's IARD as of January 4, 2016.

[43] Client assets are not part of the adviser's balance sheet. Client assets are not subject to the liquidation or potential bankruptcy process of an asset manager and are not subject to the adviser's creditors.

[44] We note that to the extent a new adviser does not have a relationship with the same custodian used by the previous adviser, assets may need to be transferred to a different custodian. Additionally, we note that complications could arise with respect to the transfer of shareholder records when transitioning client accounts to another adviser.

We are also aware of transitions involving funds under stress that have not been seamless or without problem.[48] For example, in one instance, an adviser's proprietary system used on behalf of a fund client had limitations on the pricing of fund shares that could not be efficiently modified to accommodate certain events, which in turn impeded the processing of fund redemption transactions and the reconciliation, liquidation, and transfer of investor accounts on a timely basis.[49] In addition, while maintaining assets with a custodian may ease the transfer of those assets, the adviser may have important or private information concerning its clients or their strategies and goals that would need to be transitioned securely and efficiently.[50]

Moreover, the 2008 financial crisis illustrated that one firm's distress may at times have a broader impact on the financial markets and overall economy.[51] Advisers could be impacted by broader market events in a number of ways that could affect an adviser's ability to continue operations and possibly lead to a transition event. For example, advisers are often owned by or affiliated with other financial services firms who themselves may be in distress. An adviser may be affected by such distress to the extent the distress negatively impacts the adviser's reputation, if it relies on a distressed affiliate for certain systems or services, or if it is an asset that a distressed parent sells.[52] Under circumstances such as these, we are concerned about the adviser's ability to continue to act in the clients' best interests.

Proper planning and preparation for possible distress and other significant disruptions in an adviser's operations is essential so that, if an entity has to exit the market, it can do so in an orderly manner, with minimal or no impact on its clients. As discussed above, an adviser's fiduciary duty obligates it to take steps to protect client interests from being placed at risk as a result of the adviser's inability to provide advisory services and, thus, it would be fraudulent and deceptive for an adviser to hold itself out as providing advisory services unless it has taken such steps.[53] Such advance planning and preparation may minimize an adviser's exposure to operational and other risks and, therefore, lessen the possibility of a significant disruption in its operations, and also may lessen any potential impact on the broader financial markets. Accordingly, and as discussed in more detail below, we believe that SEC-registered advisers should be required to adopt and implement a written business continuity and transition plan that is tailored to the risks associated with the adviser's operations and includes certain components, reflecting its critical role as an agent for its clients.

C. Discussion

We believe it is appropriate at this time to propose a rule requiring SEC-registered advisers to adopt and implement a business continuity and transition plan[54] that is reasonably designed to address operational and other risks related to a significant disruption in an adviser's operations and that addresses certain specified components.[55] We recognize that, pursuant to the Compliance Program Rule, most SEC-registered investment advisers may already have BCPs in place as part of their compliance policies and procedures[56] and that those plans (or other plans) may also address transition planning.[57] However, it has been our staff's experience that the robustness of these BCPs is inconsistent across investment advisers. We believe that requiring a business continuity and transition plan that addresses operational and other risks by rule and specifying certain components of such a plan will facilitate the adoption and implementation of robust plans by all SEC-registered investment advisers that address critical areas and that should be effective and workable during a significant disruption in an adviser's operations. Moreover, we believe requiring such plans will benefit advisory clients because advisers will likely be better prepared to deal with business continuity and transition events if and when they occur and will better mitigate risks attendant with their operations and business practices, thereby reducing the likelihood of client harm as the result of a significant disruption in an adviser's operations.

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[45] For example, although a unique situation, advisory firm Neuberger Berman spun out of Lehman Brothers during the 2008 financial crisis into a private company. *See also infra* note 52 (discussing the circumstances of the Neuberger Berman sale).

[46] *See supra* note 41.

[47] *See, e.g.,* Trevor Hunnicutt, *F-Squared Files for Bankruptcy,* Investment News (July 8, 2015) ("F-Squared Article"), *available at http://www.investmentnews.com/article/20150708/FREE/150709926/f-squared-files-for-bankruptcy* (noting that after settling charges with the SEC for false performance claims, F-squared started losing assets under management); Christine Dugas & Sandra Block Strong, *Strong Capital, Founder to Pay $140M in Settlement,* USA Today (May 20, 2004), *available at http://usatoday30.usatoday.com/money/perfi/funds/2004-05-20-strong-settle_x.htm* (noting that after Strong Capital Management ("Strong") and its founder settled charges with the SEC for allowing and engaging in undisclosed frequent trading in Strong mutual funds, Strong funds had a "net outflow of investor assets totaling $4.9 billion"); *see also* In the Matter of F-Squared Investments, Inc., Advisers Act Rel. No. 3988 (Dec. 22, 2014) (settled enforcement action); In the Matter of Strong Capital Management, *et al.,* Securities Exchange Act Rel. No. 49741 (May 20, 2004) (settled enforcement action); *infra* note 60.

[48] *See, e.g.,* BlackRock FSOC Comment Letter (citing to the wind-down of Long-Term Capital Management in 2000 and Reserve Primary Fund in 2008 and noting that regulatory intervention was necessary for the funds involved).

[49] *See* In the Matter of The Reserve Fund, *et al.,* Investment Company Act Rel. No. 28386 (Sept. 22, 2008) (finding that the temporary suspension of the right of redemption and postponement of payment for shares which had been submitted for redemption but for which payment had not been made was necessary for the protection of shareholders); *see also The Reserve Delays Primary Fund Distributions,* MFWire.com (Oct. 14, 2008), *available at http://www.mfwire.com/article.asp?storyID=19638&bhcp=1* ("The process of determining accurately the number of shares each investor held in the Primary Fund has proven to be extremely complex and could not be completed in the originally anticipated time frame."); *The Reserve Furnishes More Details On Primary Fund Redemptions,* MFWire.com (Oct. 16, 2008), *available at http://www.mfwire.com/article.asp?storyID=19656&bhcp=1* ("[W]e have been working diligently to enhance our existing software and add new programs to hasten the distribution process.").

[50] *See generally* Regulation S–P, 17 CFR 248 (establishing general requirements and restrictions on a financial institutions' ability to disclose nonpublic personal information about consumers, including clients, to nonaffiliated third parties and exceptions associated therewith).

[51] *See generally* Joint Report, *infra* note 72.

[52] *See, e.g.,* Lehman Brothers selling its asset management arm after declaring bankruptcy. Sam Mamudi, *Neuberger Berman Sold to Private Equity,* Market Watch (Sept. 29, 2008), *available at http://www.marketwatch.com/story/neuberger-berman-sold-to-private-equity-for-215-billion.*

[53] *See supra* section I.A; *see also* section 206(4) of the Advisers Act.

[54] We recognize that business continuity planning and transition planning address different circumstances (*i.e.* one addresses the continuation of a business while the other addresses the winding down of a business). *See infra* note 60 and accompanying text. However, both business continuity planning and transition planning pertain to instances where an adviser may be unable to provide advisory services and where advance planning for those instances would benefit advisers and their clients. In this release and in proposed rule 206(4)–4, we refer to an adviser adopting "a" business continuity and transition plan. The proposed rule would not require an adviser to consolidate all of the components described in proposed rule 206(4)–4 into one document. An adviser may maintain separate plans that address the components identified in proposed rule 206(4)–4.

[55] We note that the Commission has explicitly required BCPs in other contexts, and that FINRA has adopted specific rules on BCPs for broker-dealers. *See* Regulation SCI Adopting Release, *supra* note 17; FINRA Rule 4370. Further, NASAA has also issued a model rule for states to apply to state-registered advisers, which tend to be smaller in scale and size than advisers registered with the Commission. *See* NASAA Model Rule 203(a)–1A.

[56] *See, e.g.,* BlackRock FSOC Comment Letter at 10 (noting that asset managers maintain BCPs); Fidelity FSOC Comment Letter at 32–33 (discussing BCPs).

[57] We understand that in practice, adviser BCPs focus on risks from events that would limit or impact normal operations, such as natural disasters or systems failures, but also can address transition planning. *See supra* note 39 (discussing the Compliance Program Adopting Release and language therein regarding risks to clients if an adviser ceases operations).

We are proposing new rule 206(4)–4 under the Advisers Act and amendments to rule 204–2 under the Advisers Act. Under rule 206(4)–4, it would be unlawful for an SEC-registered investment adviser to provide investment advice unless the adviser adopts and implements a written business continuity and transition plan and reviews that plan at least annually. The proposed amendments to rule 204–2 would require those advisers to make and keep copies of all written business continuity and transition plans that are in effect or were in effect at any time during the last five years, as well as any records documenting the adviser's annual review of its business continuity and transition plan.

1. Adopt and Implement Business Continuity and Transition Plans

The proposed rule would require SEC-registered advisers to adopt and implement written business continuity and transition plans reasonably designed to address operational and other risks related to a significant disruption in the investment adviser's operations.[58] These plans would include policies and procedures concerning (1) business continuity after a significant business disruption, and (2) business transition in the event the investment adviser is unable to continue providing investment advisory services to clients. Business continuity situations generally include natural disasters, acts of terrorism, cyber-attacks, equipment or system failures, or unexpected loss of a service provider, facilities, or key personnel. Business transitions generally include situations where the adviser exits the market and thus is no longer able to serve its clients, including when it merges with another adviser, sells its business or a portion thereof,[59] or in unusual situations, enters bankruptcy proceedings.[60]

The proposed rule is intended to help ensure that an adviser's policies and procedures minimize material service disruptions and any potential client harm from such disruptions. Advisers should keep this focus at the forefront when reviewing their business operations and developing their policies and procedures. Accordingly, the proposed rule would require an SEC-registered adviser's business continuity and transition plan to include policies and procedures designed to minimize material service disruptions, including policies and procedures that address certain specific components. We recognize that advisers' business models and operations vary, but we believe that every business continuity and transition plan must generally address operational and other risks related to a significant disruption in the adviser's operations and must address certain key components to plan and prepare for such disruptions.[61] While we believe advisers should generally assess and inventory all of the components of their businesses in order to develop their business continuity and transition plans and tailor their plans to the specific risks their businesses face, we also believe that identifying these key components should facilitate the adoption and implementation of robust BCPs by all SEC-registered investment advisers.

Under the proposed rule, the content of an SEC-registered adviser's business continuity and transition plan would be based upon risks associated with the adviser's operations and would include policies and procedures designed to minimize material service disruptions, including policies and procedures that address the following:[62] (1) Maintenance of critical operations and systems, and the protection, backup, and recovery of data;[63] (2) pre-arranged alternate physical location(s) of the adviser's office(s) and/or employees;[64] (3) communications with clients, employees, service providers, and regulators;[65] (4) identification and assessment of third-party services critical to the operation of the adviser;[66] and (5) plan of transition that accounts for the possible winding down of the adviser's business or the transition of the adviser's business to others in the event the adviser is unable to continue providing advisory services.[67]

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[58] *See* proposed rule 206(4)–4. We note that adviser BCPs are also often referred to as business continuity and disaster recovery plans; however, we have chosen to use the term "business continuity and transition plan" to refer to plans required under the proposed rule. We believe, however, that such plans would encompass disaster recovery planning because any robust BCP would need to plan for the recovery of its business operations and systems in order to be able to continue providing services to clients. *See* proposed rule 206(4)–4(b)(2)(i) (requiring business continuity and transition plans to include maintenance of critical operations and systems, and the protection, backup, and recovery of data).

[59] *See* proposed rule 206(4)–4(b). We note with respect to business transitions that there may be circumstances where an adviser is unable to provide advisory services for only a portion of its business, but is able to continue providing services with respect to another portion of its business, and thus, only exits a particular market. An adviser's business continuity and transition plan generally should address the possibility of such a partial transition. *Cf. infra* note 60 and accompanying text (discussing business transitions generally).

[60] For example, in 2015, F-Squared Investments, Inc. filed for bankruptcy and arranged for its investment strategies to be managed by another adviser. *See* F-Squared Article, *supra* note 47. In addition, in 2005, funds managed by Strong were acquired by Wells Fargo & Company and the "legal entities comprising the Strong . . . complex were subsequently liquidated." *See* BlackRock FSOC Comment Letter at 62–63 (discussing the Strong transition); *see also* Press Release, *Wells Fargo Agrees to Acquire $34 Billion in Assets Under Management From Strong Financial Corporation*, Wells Fargo (May 26, 2004), *available at http://www.wellscap.com/docs/press_releases/5.26.04.pdf*.

[61] *See supra* notes 30–35 and accompanying text (discussing certain key elements of BCPs). Other regulatory bodies and organizations also have recognized key elements of business continuity plans. *See* 17 CFR 23.603 (setting forth essential components of BCPs for swap dealers and major swap participants); FINRA Rule 4370 (setting forth minimum elements that a business continuity plan should address); NASAA Model Rule 203(a)–1A (stating certain elements the plan should address); FFIEC Handbook, *supra* note 17, at G–1 (discussing components of effective BCPs).

[62] We have modeled the proposed rule on BCP requirements for other financial services firms that we believe share similar vulnerabilities as investment advisers, as well as our staff's examinations experiences, which have highlighted a number of best practices as well as a number of areas for improvement specific to investment advisers. For example, to assist advisers in considering their own business continuity issues, the examination staff previously identified a number of "lessons learned" from its examinations of advisers that were affected by Hurricane Katrina. *See* Compliance Alert, *supra* note 30. The staff noted certain provisions in disaster recovery plans that appeared to be effective in allowing an adviser to provide "uninterrupted advisory services to clients in a compliant manner after a disaster" including (i) a pre-arranged remote location for short-term and possible long-term use; (ii) alternate communication protocols to contact staff and clients; (iii) remote access to business records and client data through appropriately secured means; (iv) temporary lodging for key staff where necessary and effective training of staff on how to fulfill essential duties in the event of a disaster; (v) maintaining accurate and up-to-date contact information for all third-party service providers and familiarity with the BCPs of those providers; (vi) contingency arrangements for loss of key personnel; (vii) periodic testing, evaluation and revision of the plan; and (viii) maintaining sufficient insurance and financial liquidity to prevent any interruption of the performance of compliant advisory services.

[63] *See* proposed rule 206(4)–4(b)(2)(i).

[64] *See* proposed rule 206(4)–4(b)(2)(ii).

[65] *See* proposed rule 206(4)–4(b)(2)(iii).

[66] *See* proposed rule 206(4)–4(b)(2)(iv).

While each SEC-registered adviser's business continuity and transition plan must address the components set forth in the proposed rule, we recognize that the degree to which an adviser's plan addresses a required component will depend upon the nature of each particular adviser's business. We also recognize that business models and operations vary significantly among advisers.[68] The proposed rule thus would require that the plan be reasonably designed to address the operational and other risks of an adviser and thus advisers need only take into account the risks associated with its particular operations, including the nature and complexity of the adviser's business, its clients, and its key personnel.[69] For example, we believe that the business continuity and transition plan of a large adviser with multiple locations, offices, or business lines likely would differ significantly from that of a small adviser with a single office or only a few investment professionals and employees. Additionally, we believe that the business continuity and transition plan of an adviser with a complex internal technology infrastructure likely would differ from that of an adviser that primarily uses an outsourced model.[70] The complexity and risks associated with these diverse business models could be substantially different, and our proposed rule is designed to give advisers the flexibility to create business continuity and transition plans that accommodate such differences.

a. Maintenance of Critical Operations and Systems, and the Protection, Backup, and Recovery of Data, Including Client Records

The proposed rule would require advisers' business continuity and transition plans to include policies and procedures on the maintenance of critical operations and systems, and the protection, backup, and recovery of data, including client records.[71] With respect to maintaining critical operations/systems, an adviser's plan generally should identify and prioritize critical functions, operations, and systems and consider alternatives and redundancies to help maintain the continuation of operations in the event of a significant business disruption.[72] When evaluating which operations and systems are critical, advisers generally should consider those that are utilized for prompt and accurate processing of portfolio securities transactions on behalf of clients, including the management, trading, allocation, clearance and settlement of such transactions. Advisers generally should also consider operations and systems that are critical to the valuation and maintenance of client accounts, access to client accounts, and the delivery of funds and securities. This typically will include identification and assessment of third-party services that support certain functions, as activities conducted may involve systems and processes that the adviser controls and others that may be wholly or partially dependent on third-party vendors, which we address below. Advisers generally also should identify which key personnel either provide critical functions to the adviser or support critical operations or systems of the adviser such that the temporary or permanent loss of those individuals would disrupt the adviser's ability to provide services to its clients.

We believe that by considering alternatives and redundancies for critical operations and systems in advance of significant business disruptions, an adviser will be able to prioritize, recover, and resume key aspects of its business in a timely manner and consequently be better able to act in its clients' best interests and continue providing services to its clients during such a disruption.[73] For example, if most securities operations functions (post-trade processing, corporate actions, reconciliation, etc.) are handled internally by the adviser,[74] then the adviser's plans should address the backup systems or other alternative processes or procedures that will be used or followed in the event of a business disruption where standard operations may not be available. Additionally, we believe that contingency plans with respect to key personnel generally should address both the temporary or permanent loss of such personnel. For example, loss of key personnel could result from an employee's sudden departure from the adviser or could be due to a weather related event that renders the employee temporarily unavailable. Accordingly, an adviser's business continuity and transition plan generally should include short-term arrangements, such as which specific individuals would satisfy the role(s) of key personnel when unavailable, and long-term arrangements regarding succession planning and how an adviser will replace key personnel.[75]

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[67] As discussed more below, the plan of transition would have to include (1) policies and procedures intended to safeguard, transfer and/or distribute client assets during transition; (2) information regarding the corporate governance of the adviser; (3) the identification of any material financial resources available to the adviser; (4) policies and procedures facilitating the prompt generation of any client-specific information necessary to transition each client account; and (5) an assessment of the applicable law and contractual obligations governing the adviser and its clients, including pooled investment vehicles, implicated by the adviser's transition. *See* proposed rule 206(4)–4(b)(2)(v).

[68] *See* Comment Letter of Wellington Management Group LLP to FSOC Notice (Mar. 25, 2015) at 2 (“The unique characteristics of today's asset management industry (agency and advice based: Low barriers to entry: High substitutability among managers: And highly competitive) result in a large number of asset management firms that are organized in a variety of models.”).

[69] *See, e.g.,* BlackRock FSOC Comment Letter at 9 (noting that “understanding the differences in operating models is crucial” in assessing the potential operational risk of an asset manager).

[70] *Id.* at 71. A larger adviser may conduct (insource) some or all middle and back office functions (*e.g.,* securities administration, accounting, and recordkeeping) internally. Whereas in an outsourced model, the asset management firm hires third-party providers to perform various middle and back office functions.

[71] We note that Regulation SCI also includes requirements regarding the maintenance of systems. Rule 1001(a) requires each SCI entity to establish, maintain, and enforce policies and procedures that are reasonably designed to ensure that its “SCI systems” have levels of capacity, integrity, resiliency, availability, and security, adequate to maintain the SCI entity's operational capability and promote the maintenance of fair and orderly markets. Moreover, rule 1001(a)(2)(v) also requires that these policies and procedures include business continuity and disaster recovery plans that are reasonably designed to achieve two-hour resumption of “critical SCI systems” following a wide-scale disruption. 17 CFR 242.1001. We note that in the Regulation SCI Adopting Release, the Commission stated that it would monitor and evaluate the implementation of Regulation SCI, the risks posed by systems of other market participants, and the continued evolution of the securities markets, and in the future may consider extending the types of requirements in Regulation SCI to other market participants, including investment advisers. *See* Regulation SCI Adopting Release, *supra* note 17, at 72259. We note that the proposed rule would not apply Regulation SCI to investment advisers. Rather, the Commission is proposing this rule in light of the specific operations and businesses of investment advisers and the risks they present.

In addition to Regulation SCI, we note, as discussed above, that our staff has previously highlighted the importance of access to business records and client data as well as backup servers and other telecommunications services in the context of business continuity planning. *See supra* notes 30 and 33, and accompanying text. We also note that other regulatory bodies and organizations have stressed the importance of critical systems and data protection in the context of BCPs. *See, e.g.,* 17 CFR 23.603(b)(1), (4) and (6) (requiring BCPs to include identification of documents, data, facilities and infrastructure, as well as backup or copying of documents and data, essential to operations, and procedures for and the maintenance of backup facilities, systems and infrastructure); FINRA Rule 4370(c)(1) and (2) (requiring BCPs to address data backup and recovery (both hard copy and electronic) as well as mission critical systems); NASAA Model Rule 203(a)–1A(1) (stating that BCPs should provide for “protection, backup and recovery of books and records”); SIFMA, Business Continuity Planning Expanded Practices Guidelines (Apr. 2011) (“SIFMA Guidelines”) at 27 and 32, *available at http://www.sifma.org/uploadedfiles/services/bcp/sifma-bc-practices-guidelines2011–04.pdf* (noting that businesses should ensure “the functionality and availability of critical business applications” and “that redundant copies of vital records” are securely stored and available during an emergency).

[72] Following the publication of the Interagency Paper, the Commission, together with the Federal Reserve and the Office of the Comptroller of the Currency, issued a joint report that discussed the industry's efforts to implement the recommendations contained in the Interagency Paper (“Joint Report”). The Joint Report notes that the Interagency Paper addresses reasonable recovery time objectives and identifies specific risk-based recovery standards in order “to assure that there will be a relatively consistent degree of preparedness across” the industry. *See* Joint Report on Efforts of the Private Sector to Implement the Interagency Paper on Sound Practices to Strengthen the Resilience of the U.S. Financial System (Apr. 2006) at 3, *available at https://www.sec.gov/news/press/studies/2006/soundpractices.pdf; see also* MFA FSOC Comment Letter at 45 (citing to the MFA's recommendations to hedge fund managers that they design and implement business continuity/disaster recovery plans “reasonably designed to: (1) Identify and prioritize critical business functions. . .”).

[73] Investment advisers should also generally consider in their business continuity planning circumstances in which a service provider (including another investment adviser that provides operations or systems to the adviser) is permanently unable to provide the adviser with critical operations or systems. *See, e.g,* Financial Conduct Authority, Outsourcing in the Asset Management Industry: Thematic Project Findings Report (Nov.

With respect to data protection, backup, and recovery, a business continuity and transition plan generally should address both hard copy and electronic backup, as appropriate.[76] A reasonably designed business continuity and transition plan generally should recognize that significant business disruptions may prevent access to electronic copies of data (*e.g.,* power or internet outage) and hard copies of data (*e.g.,* cannot access building where data is located). Such a plan should also recognize the important role electronic records can play in carrying out the adviser's plan of transition in a timely manner.

Additionally, in connection with data backup and recovery, a business continuity and transition plan generally should include an inventory of key documents (*e.g.,* organizational documents, contracts, policies and procedures), including the location and description of the item, and a list of the adviser's service providers relationships that are necessary to maintaining functional operations. This documentation generally should include details of the adviser's management structure, risk management processes, and financial and regulatory reporting requirements. We believe such documentation would make it easier for an adviser and its employees to access important operations/systems, documents, and relationships during a significant business disruption.

Finally, we note with respect to data protection, backup and recovery, one type of potentially significant business disruption is a cyber-attack. An adviser generally should consider and address as relevant the operational and other risks related to cyber-attacks.[77] We believe exposure to compliance and operational risks that may be caused by cybersecurity incidents can be mitigated by addressing such risks in the context of business continuity planning.[78]

b. Pre-Arranged Alternate Physical Location(s)

The proposed new rule would also require an adviser's business continuity and transition plan to include pre-arranged alternate physical location(s) of its office(s) and/or employees. As our staff has indicated a number of times, alternate or remote locations are essential for an adviser to continue providing services during a significant business disruption.[79] Accordingly, when developing business continuity and transition plans, advisers generally should consider the geographic diversity of their offices or remote sites and employees, as well as access to the systems, technology, and resources necessary to continue operations at different locations in the event of a disruption.[80] For example, an adviser

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2013) ("FCA Paper"), *available at http://www.fca.org.uk/static/documents/thematic-reviews/tr13–10.pdf* ("Based on our initial assessment of asset managers last year, we concluded that firms in the sample were unprepared for a failure of their service provider."). The FCA Paper suggested that asset managers should review their own outsourcing arrangements and where appropriate (i) "enhance their contingency plans for the failure of a service provider providing critical activities, taking into account industry-led guiding principles where applicable" and (ii) "assess the effectiveness of their oversight arrangements to oversee critical activities outsourced to a service provider, making sure the required expertise is in place."

[74] As discussed above, investment advisers that are also registered broker-dealers will be subject to both the proposed rule and FINRA's rule 4370 regarding BCPs. While we believe the two rules are largely complementary, we note that SEC-registered advisers would have to comply with the requirements of proposed rule 206(4)-4 with respect to their advisory functions. *See supra* note 18.

[75] An adviser should also consider whether the departure of key personnel may trigger contractual obligations with clients, investors, or counterparties. For example, private funds clients may contain redemption rights for its investors upon the departure of specified investment personnel.

[76] This proposed requirement would be consistent with the existing requirement for SEC-registered investment advisers to maintain specific books and records relating to its investment advisory business. *See* rule 204–2(a) and (g). The "books and record" rule requires advisers to have procedures: to reasonably protect electronic records from loss, alteration, or destruction; to limit access to electronic records; and to assure that electronic records that are created from hard copy are complete, true, and legible. *See* rule 204–2(g)(3).

[77] Our staff recently highlighted a number of measures for advisers to consider in the context of cybersecurity and noted that "advisers should identify their . . . compliance obligations under the federal securities laws and take into account these obligations when assessing their ability to prevent, detect and respond to cyber attacks." *See* Cybersecurity Guidance, IM Guidance Update (Apr. 2015), *available at http://www.sec.gov/investment/im-guidance-2015–02.pdf.* In March 2014, the Commission hosted a roundtable on cybersecurity, which highlighted the Commission's focus on cybersecurity-related issues and a number of Commission actions relating to cybersecurity. The Commission is also focused on cybersecurity risk issues related to investment advisers, including data protection and identity theft vulnerabilities. *See* Chair Mary Jo White, Opening Statement at SEC Roundtable on Cybersecurity (Mar. 26, 2014), *available at http://www.sec.gov/News/PublicStmt/Detail/PublicStmt/1370541286468; see also* Identity Theft Red Flags Rules, Securities Exchange Act Rel. No. 69359 (Apr. 10, 2013); *see also* Cybersecurity Roundtable, SEC, *available at http://www.sec.gov/spotlight/cybersecurity-roundtable.shtml* (providing information on the roundtable). We also note that the National Institute of Standards and Technology ("NIST") has issued a framework for improving cybersecurity and that it recently sought comment on this framework. *See* NIST, Framework for Improving Critical Infrastructure Cybersecurity (Feb. 12, 2014), *available at http://www.nist.gov/cyberframework/upload/cybersecurity-framework-021214.pdf;* NIST, Cybersecurity Framework—Overview, *available at http://www.nist.gov/cyberframework/#* (discussing requests for comment on the cybersecurity framework).

[78] We recognize that advisers also may have additional policies and procedures to address compliance and operational risks related to cybersecurity incidents.

[79] *See supra* notes 30 and 32, and accompanying text; *see also* Regulation SCI Adopting Release, *supra* note 17 (requiring an SCI entity's business continuity and disaster recovery plan to include "geographically diverse" backup and recovery capabilities). We note that other regulatory bodies and organizations have also recognized the importance of alternate sites and geographic diversity in business continuity planning. *See, e.g.,* 17 CFR 23.603(b)(5) (requiring backup facilities, infrastructure and alternative staffing in geographically separate areas); FINRA Rule 4370(c)(6) (requiring BCPs to address "alternate physical location of employees"); NASAA Model Rule 203(a)–1A(3) (stating that BCPs should provide for "office relocation in the event of temporary or permanent loss of a principal place of business"); FFIEC Handbook, *supra* note 17, at G14 (stating that a "BCP should address site relocation for short-, medium-, and long-term disaster and disruption scenarios"); Interagency Paper, *supra* note 16 (noting that backup sites should not rely on the same infrastructure components used by the primary site, should not be impaired by a wide-scale evacuation at or the inaccessibility of staff that service the primary site, and should consider staffing needs at the backup site if the firm relies on the same labor pool for both its primary and back up sites).

[80] We are not proposing to require that an adviser's business continuity and transition plan include an alternative location at a specified distance away from its primary location because we believe, as discussed above, that an adviser's plan should be tailored to its particular operations and that, while a specified distance may be appropriate for one adviser's alternate location, it may not be appropriate for all advisers. Nonetheless, we believe advisers generally should consider whether their alternative locations are in such close proximity to each other or to its primary location that they may be sharing common infrastructure providers and

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may recognize that a significant business disruption could limit access to its primary or only office for an extended period of time and, therefore, establish a satellite office or plan to use a remote site in another location or geographic region and may also allow remote access by employees so the adviser could continue to have access to the facilities, systems, and personnel necessary to carry on its business.[81]

c. Communications With Clients, Employees, Service Providers, and Regulators

Under the proposed rule, a business continuity and transition plan would also need to address communications with clients, employees, service providers, and regulators. We believe that communication plans are an essential element of effective business continuity and transition plans and generally should cover communications with parties involved in the critical aspects of the adviser's operations.[82] For example, if an adviser's employees are unaware that a disruption has occurred and the adviser's business continuity and transition plan has been activated, the plan will likely fail. An adviser's communication plan generally should cover, among other things, the methods, systems, backup systems, and protocols that will be used for communications, how employees are informed of a significant business disruption, how employees should communicate during such a disruption, and contingency arrangements communicating who would be responsible for taking on other responsibilities in the event of loss of key personnel.[83] Adviser business continuity and transition plans generally should also address employee training, so that in the event of a significant business disruption employees understand their specific roles and responsibilities and are able to carry out the adviser's plan.

Moreover, advisers should consider when and how it is in their clients' best interests to be informed of a significant business disruption and/or its impact. Accordingly, with respect to clients, a business continuity and transition plan generally should include the process by which the adviser would have prompt access to client records that include the name and relevant contact and account information for each client as well as investors in private funds sponsored by the investment adviser.[84] These plans generally should include how clients will be made aware of and updated about a significant business disruption that materially impacts ongoing client services (*e.g.*, periodic updates to Web sites and customer service lines) and, when applicable, how clients will be contacted and advised if account access is impacted during such a disruption.

Similarly, an adviser's communication plan with its service providers generally should include, among other things, how the service provider will be notified of a significant business disruption at the adviser as well as how the adviser will be notified of a significant business disruption at a service provider, and how the entities will communicate with one another and clients or investors (where applicable)[85] during a disruption. With respect to communications with the adviser's regulators, the adviser's business continuity and transition plan generally should include the contact information for relevant regulator(s), and identify the personnel responsible for notifying, as well as under what circumstances it would notify, such regulator(s) of a significant business disruption.

d. Identification and Assessment of Third-Party Services Critical to the Operation of the Adviser

The proposed rule would require an adviser's business continuity and transition plan to include the identification and assessment of third-party services critical to the operation of the adviser.[86] We understand advisers frequently outsource certain functions or aspects of their operations or use third-parties' systems or vendors for their middle and back office functions in order to permit the adviser to focus on front office core functions, such as portfolio management and trading.[87] To the extent critical services are outsourced to third-parties, we believe that an adviser generally should be prepared for significant business disruptions that could impair its ability to act in its clients' best interests by having a business continuity and transition plan that addresses the critical services provided to it by such third parties.[88]

In this regard, an adviser's business continuity and transition plan should identify critical functions and services provided by the adviser to its clients, and third-party vendors supporting or conducting critical functions or services for the adviser and/or on the adviser's behalf.[89] An adviser generally should

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thus, that the alternative locations would be similarly affected by an external event.

[81] An adviser should consider the technology, systems, and resources necessary for employees working remotely to continue to securely conduct the adviser's business.

[82] As discussed above, our staff has previously noted the important role that communication plans can play in business continuity planning. *See supra* notes 30 and 34 and accompanying text. Additionally, we note that other regulatory bodies and organizations have focused on communications in the context of BCPs. *See, e.g.,* 17 CFR 23.603(b)(3) (requiring BCPs to include communication plans with respect to employees, vendors, and regulatory authorities); FINRA Rule 4370(c)(4), (5), and (9) (requiring BCPs to address communications with customers, employees and regulators); NASAA Model Rule 203(a)–1A(2) (stating that BCPs should provide for alternate communications with "customers, key personnel, employees, vendors, service provides. . .and regulators. . . ."); FFIEC Handbook, *supra* note 17, at G–4 (stating that "[c]ommunication is a critical aspect of a BCP and should include communication with employees, . . . regulators, vendors/suppliers (detailed contact information), [and] customers (notification procedures) . . . .").

[83] *See supra* section I.C.1.a.

[84] For a private fund to qualify for the exclusion from the definition of "investment company" in either section 3(c)(1) or 3(c)(7) of the Investment Company Act of 1940 ("Investment Company Act") or rely on various offering exemptions under the Securities Act of 1933, the private fund is already required to have a reasonable belief regarding certain qualification information with regard to its beneficial owners that are U.S. persons. *See, e.g.,* 17 CFR 270.2a51–1(h), 17 CFR 230.501(a). While the private fund may not be required to have such detailed information about non-U.S. person beneficial owners, we understand it generally has contact information readily available.

[85] For example, pooled investment vehicles generally rely on their investment advisers to arrange for and interact with fund service providers. If an adviser to an investment company, for example, outsources certain back office functions, such as transfer agency to a third-party vendor, its business continuity and transition plan should address coordination of communications with the transfer agent to investors in the fund, as well as with intermediaries servicing investors who also are beneficial owners of the fund.

[86] We note that Regulation SCI includes specific requirements with respect to the resumption of "critical SCI systems," differentiating these systems from other systems covered by the regulation. *See* 17 CFR 242.1000 and 242.1001(a)(2)(v) of Regulation SCI. In addition, as discussed above, our staff has previously noted the importance of addressing third-party relationships in the context of BCPs. *See supra* notes 30 and 33, and accompanying text. Additionally, we note that other regulatory bodies and organizations have noted that BCPs should address third-party relationships. *See, e.g.,* 17 CFR 23.603(b)(7) (requiring "identification of potential business interruptions encountered by third parties that are necessary to continued operations" and "a plan to minimize the impact"); FINRA Rule 4370(c)(7) (requiring BCPs to address "critical business constituent, bank, and counterparty impact"); SIFMA Guidelines, *supra* note 71, at 30 (stating that BCPs should include internal and external business partners and that firms should be familiar with the BCPs and risks of those partners).

[87] For example, we frequently see middle office functions such as administration of the front office and trades and related transactions, including securities operations and processing (confirmation, routing, matching, and settlement trades), pricing/valuation, reconciliation (both cash and positions), and post trade compliance and reporting, outsourced to third parties.

[88] The nature of advisory business is such that advisers typically depend on a number of third-party service providers and systems vendors (*e.g.,* broker-dealers, custodians, etc.) in providing services to their clients.

[89] The Joint Report noted that, notwithstanding the use of a service provider to perform various

consider a variety of factors when identifying and prioritizing which service providers should be deemed critical, such as the day-to-day operational reliance on the service provider and the existence of a backup process or multiple providers, whether or not the service provided includes direct contact with clients or investors, and whether the service provider is maintaining critical records or able to access personally identifiable information, among other things. We would generally consider critical service providers to at least include those providing services related to portfolio management, the custody of client assets, trade execution and related processing, pricing, client servicing and/or recordkeeping, and financial and regulatory reporting.

Once an adviser identifies its critical service providers, it should review and assess how these service providers plan to maintain business continuity when faced with significant business disruptions and consider how this planning will affect the adviser's operations.[90] For example, if an adviser's business continuity and transition plan contemplates that it will rely on a particular service provider for a critical service, the adviser generally should be aware of whether the service provider has a BCP and if that BCP provides alternatives, including backup plans, to allow it to continue providing critical services during a significant business disruption. If the service provider does not have a BCP or if its BCP does not provide for such alternatives, the adviser generally should consider alternatives for such critical services, which may include other service providers or internal functions or processes that can serve as a backup or contingency for such critical services.[91]

We also recognize that advisers often play a key role in identifying, arranging for, and overseeing other service providers for certain of their clients as part of their sponsoring roles. For example, an adviser may arrange for a particular administrator or pricing vendor for a registered investment company client or private fund client.[92] Accordingly, we believe an adviser should generally review and assess how the critical service providers it arranges and/or oversees for its clients plan to maintain business continuity when faced with significant business disruptions and consider how this planning will affect its clients' operations.[93]

We understand that many advisers currently take a variety of steps to understand the operational and other risks of their service providers and those of certain clients' critical service providers,[94] such as reviewing a summary of a service provider's BCP, due diligence questionnaires, an assurance report on controls by an independent party,[95] certifications or other information regarding a provider's operational resiliency or implementation of compliance policies, procedures, and controls relating to its systems, results of any testing, and conducting onsite visits. Factors such as the significance of the service provider to advisory operations, the type of service provided, and the adviser's ability to require or request actions of its service providers will impact the steps that advisers should consider taking.

e. Transition Plan

Under the proposed rule, an adviser's business continuity and transition plan would have to include a plan of transition that accounts for the possible winding down of the adviser's business or the transition of the adviser's business to others in the event the adviser is unable to continue providing advisory services.[96] Advisers facing the decision to exit the market commonly do so by: (1) Selling the adviser or substantially all of the assets and liabilities of the adviser, including the existing advisory contracts with its clients, to a new owner; (2) selling certain business lines or operations to

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activities, a firm "cannot shift responsibility for compliance and risk management to the service provider. . . . Should a service provider not have the appropriate level of resilience, a financial institution would be required to move to a provider that can demonstrate an appropriate level of resilience." *See* Joint Report, *supra* note 72 at 6.

We also encourage advisers to be familiar with the terms of their contracts with critical service providers, including any provisions regarding the termination or assignment of the contract and any notice requirements related to those provisions.

[90] In late August 2015, Bank of New York Mellon ("BNY Mellon"), a service provider that provides custodial and administrative services to mutual funds, closed-end funds, and exchange-traded funds, experienced a breakdown in one of its third-party systems (SunGard's InvestOne) used to calculate numerous client funds' net asset values ("NAVs"). As a result of this breakdown, BNY Mellon was unable to deliver timely system-generated NAVs to certain clients for several days, which resulted in certain clients pricing their shares using stale or manually calculated NAVs and certain ETFs using stale baskets. Once the automated system was restored, ETF baskets were updated and certain funds had to review the NAVs used while the automated system was down and make any necessary corrections. *See, e.g.*, Stephen Foley, *BNY Mellon Close to Resolving Software Glitch*, Financial Times (Aug. 31, 2015), *available at http://www.ft.com/intl/cms/s/0/47d5860a-4f2b-11e5-b029-b9d50a74fd14.html*; Jessica Toonkel & Tim McLaughlin, *BNY Mellon Pricing Glitch Affects Billions of Dollars of Funds*, Reuters (Aug. 26, 2015), *available at http://www.reuters.com/article/bnymellon-funds-nav-idUSL1N1111QY20150826*; Barrington Partners White Paper, An Extraordinary Week: Shared Experiences from Inside the Fund Accounting System Failure of 2015 (Nov. 2015), *available at http://www.mfdf.org/images/uploads/blog_files/SharedExperiencefromFASystemFailure2015.pdf*; Transcript of the BNY Mellon Teleconference Hosted by Gerald Hassell on the Sungard Issue, *available at https://www.bnymellon.com/_global-assets/pdf/events/transcript-of-bny-mellon-teleconference-on-sungard-issue.pdf*.

[91] We recognize that it may not be feasible or may be cost prohibitive for an adviser to retain backup service providers, vendors, and/or systems for all critical services. In such cases, an adviser should consider backup plans, functions and/or processes to address how it will manage the loss of a critical service.

[92] *See supra* note 85.

[93] *See, e.g., supra* note 89.

[94] *See, e.g.*, BlackRock FSOC Comment Letter; *see also* Risk Principles for Asset Managers, *supra* note 4, at 19 ("The increased level of outsourcing to third party service providers has changed not only their outsourcing risk profile but such significant changes to an organization's business model can lead to many process and control changes and could therefore increase the exposure to other (operational) risk areas (*e.g.*, country risk and service provider oversight)"); *cf.* rule 38a–1(a)(2) (requiring registered investment company boards to approve policies and procedures that provide for the oversight of compliance by the fund's investment adviser and certain other named service providers). Such approval must be based on a finding that the policies and procedures are reasonably designed to prevent violations of the federal securities laws by the fund, the investment adviser and the other named service providers. *See id.*

[95] *See* Investment Company Institute, Financial Intermediary Controls and Compliance Assessment Engagements (Dec. 2015) at 8, *available at https://www.ici.org/pdf/ppr_15_ficca.pdf* (identifying a financial intermediary's "Business Continuity/Disaster Recovery Program" as one of 17 areas of focus that "should be addressed on an annual basis as part of the financial intermediary's controls and compliance engagements."); *see also* AICPA, Reporting on Controls at a Service Organization (2015), *available at http://www.aicpa.org/Research/Standards/AuditAttest/DownloadableDocuments/AT-00801.pdf*. Many advisers review SSAE 16 reports that are prepared by an independent public accountant in accordance with the American Institute of CPAs' Auditing Standards Boards' Statement on Standards for Attestation Engagements No. 16, Reporting on Controls at a Service Organization. These reports provide assurances that the service provider has established a system of internal controls, that the internal controls are suitably designed to achieve specified objectives, and that the internal controls are operating effectively.

[96] *Cf.* FINRA Rule 4370(c)(10) (requiring BCPs to address "[h]ow the member will assure customers' prompt access to their funds and securities in the event that the member determines that it is unable to continue its business"); NASAA Model Rule 203(a)–1A(4) (stating that BCPs should provide for the "[a]ssignment of duties to qualified responsible persons in the event of the death or unavailability of key personnel"). Transition of an adviser's business to others generally would, for example, include a situation where the adviser is a sole proprietor who is no longer able to provide advisory services and is, therefore, transferring its business to another person/firm or winding down operations entirely. Such succession/transition planning generally should be accounted for in the context of an adviser's plan of transition.

another adviser;[97] or (3) the orderly liquidation of fund clients or termination of separately managed account relationships.[98] Regardless of the method an adviser chooses to effect a transition, we believe that assessing and planning for potential impediments associated with that method should help an adviser act in its clients' best interests by seeking to mitigate potentially negative effects on its clients and investors.[99]

We believe that a plan of transition generally should account for transitions in both normal and stressed market conditions,[100] and generally should consider each type of advisory client, the adviser's contractual obligations to clients, counterparties, and service providers, and the relevant regulatory regimes under which the adviser operates.[101] Under the proposed rule, the transition components of a business continuity and transition plan would have to include (1) policies and procedures intended to safeguard, transfer and/or distribute client assets during transition; (2) policies and procedures facilitating the prompt generation of any client-specific information necessary to transition each client account; (3) information regarding the corporate governance structure of the adviser; (4) the identification of any material financial resources available to the adviser; and (5) an assessment of the applicable law and contractual obligations governing the adviser and its clients, including pooled investment vehicles, implicated by the adviser's transition. Each of the proposed required components of an adviser's transition plan is designed to help an adviser be well prepared for a transition so that it can act quickly and in its clients' best interests if and when a transition occurs.

We believe that preserving the safety of client assets and the ability to promptly produce and transfer the information necessary for the ongoing management of client assets is fundamental to an adviser acting in the best interests of its clients. The adviser's policies and procedures addressing how the adviser intends to safeguard, transfer and/or distribute client assets in the event of a transition generally should consider the unique attributes of each type of the adviser's clients (*e.g.*, registered investment companies, private funds, separately managed accounts) and how the adviser plans to transfer accurate client information to other advisers or their service providers. For example, the transfer of client information with respect to registered investment companies and private funds may be more complex than that of separately managed accounts because registered investment companies and private funds typically have multiple investors, whereas separately managed accounts typically have only one investor.

It is our understanding that the methods for safeguarding, transferring, and/or distributing client assets may vary by client type and that the best method for one client might not be the best method for another.[102] Thus, we believe an adviser's policies and procedures should appropriately account for the different methods in which it plans to safeguard, transfer, and/or distribute assets of its different types of clients. Additionally, if a client account holds assets that would require special instruction or treatment in the event of transition, an adviser's policies and procedures generally should address such instruction or treatment.[103]

Further, the transition plan should also contain policies and procedures that would facilitate the prompt generation of any client-specific information necessary to transition a client account, such as the identity of custodians, positions, counterparties, collateral, and related records of each client. Similar to the need to have accurate and accessible client information in the event of a business continuity scenario, we believe that this information is necessary to effect a smooth transition of the management of client accounts.

We believe senior executives at an investment adviser generally, and especially in times of stress, should be able to quickly identify the important decision-makers within the organization and understand the inter-relationships between the adviser and any affiliated entities to be able to assess whether and how issues at an affiliate may affect the advisory entity. For example, an adviser that uses an affiliate as a qualified custodian may face additional issues if the transition event is related to that affiliate's operations. We believe that this information is necessary if the adviser needs to assess the manner in which it can exit the market with minimal adverse effect on its clients or to take steps necessary to protect itself from issues that may stem from an affiliated entity. Accordingly, with respect to the adviser's corporate governance structure, the transition component of a business continuity and transition plan generally should include an organizational chart and other information about the adviser's ownership and management structure, including the identity and contact information for key personnel, and the identity of affiliates (both foreign and domestic) whose dissolution or distress could lead to a change in or material impact to the adviser's business operations.[104]

Registered investment advisers manage a variety of products and security types, with investments in and investors from various jurisdictions and are subject to a variety of contractual and legal obligations and regulatory regimes. An adviser's ability to seamlessly transition advisory services could be impacted by its or its clients' contractual obligations or the various regulatory regimes under which the adviser or its advisory client may be subject. For example, an adviser's insolvency or termination may trigger a termination clause in a client's derivative contract.[105] Also, the board and shareholders of a registered investment company must approve an advisory contract with any new adviser[106] and the Advisers Act requires advisory contracts to include a provision that a contract cannot be assigned without client consent.[107] Other regulatory regimes may require regulatory approval for certain acts,[108] which may be further complicated by the need for cross-border cooperation if the adviser operates in multiple jurisdictions[109] or the adviser's pooled investment vehicle clients are domiciled in different jurisdictions.[110] Accordingly, we are proposing that an adviser's transition plan include an assessment of the applicable law and contractual obligations governing the adviser and its clients, including pooled investment vehicles, implicated by the adviser's transition.

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[97] *See supra* note 59 (discussing partial transitions of an adviser's business).

[98] *See, e.g.*, Prudential Financial Inc. 2014 Resolution Plan: Public Section (June 30, 2014), *available at http://www.federalreserve.gov/bankinforeg/resolution-plans/prudential-fin-1g-20140701.pdf*; American International Group, Inc. Resolution Plan Section 1: Public Section (July 1, 2014), *available at http://www.federalreserve.gov/bankinforeg/resolution-plans/aig-1g-20140701.pdf*. These two nonbank financial companies have been designated "systemically" important by FSOC and also have investment adviser subsidiaries. The publicly-available summaries of their resolution plans filed with the Federal Reserve indicate that they would seek to either sell their advisory businesses or seek Chapter 11 bankruptcy proceedings for their advisory entities.

[99] An adviser may also wish to consider in the context of its transition plan, if and when it would be appropriate to use a transition manager. A transition manager facilitates and coordinates "the transition of asset management from one manager to another, or from one asset class or investment strategy to another." *See supra* note 41.

[100] *See supra* notes 38–39 and accompanying text (discussing the 2008 financial crisis and transition planning generally).

[101] In addition to contractual obligations to its clients and vendors, an adviser that provides other services to entities, such as to another adviser, generally should consider its contractual obligations as a service provider to those other entities as it plans for a transition event.

[102] For example, if the adviser manages registered investment companies, the investment companies' board(s) may determine that the best method for transferring the assets of these funds is to reorganize them into funds managed by a new adviser. Separately managed accounts, however, would not be reorganized, but may have other considerations unique to them, such as whether a new custodian would be necessary for a new adviser.

[103] For example, it is our understanding that when transitioning accounts from one adviser to another, derivatives positions require special treatment in that they are typically unwound rather than transferred to the new adviser and that the terms of the derivatives instrument may dictate whether and how such unwinding takes place.

[104] An advisory entity may be adversely affected by an affiliate's distress if, for example, the adviser and distressed affiliate share systems, personnel, sources of financing, or similar names.

Finally, we believe it is important for an adviser to have considered in advance its strategy for either avoiding or facilitating a transition of its business and client accounts in the event the adviser is in material financial distress such that its ability to continue providing advisory services to its clients or otherwise acting in its clients' best interests could be impacted or undermined.[111] Accordingly, the proposed rule requires that the adviser's plan of transition consider any material financial resources available to the adviser. For example, the adviser could identify any material sources of funding, liquidity, or capital it would seek in times of stress in order to continue operating[112] or consider how it would implement a reduction of expenses or other alternatives.

f. Request for Comment

We seek comment on the proposed requirement to adopt and implement a business continuity and transition plan, and the proposed components of that plan.

- Should we require all SEC-registered advisers to adopt and implement business continuity and transition plans? Or should we identify only a subset of SEC-registered advisers that must implement such plans? Which advisers should be in such a subset (*e.g.,* large advisers with assets under management over a specific threshold, advisers affiliated with financial institutions, etc.) and why?
- Rather than adopting the proposed rule, should the Commission issue guidance under rule 206(4)–7 under the Advisers Act addressing business continuity and transition plans? If so, should that guidance set forth possible elements of such a plan?
- What, if any, implications will the proposed rule have for investment advisers that are also subject to other regulatory requirements as to business continuity and/or transition planning (*e.g.,* FINRA or CFTC rules on BCPs)? For example, would the proposed rule be inconsistent with an adviser's obligations under other regulatory requirements?
- Should we require business continuity and transition plans to include each of the proposed components? Alternatively, should the rule require advisers to have a business continuity and transition plan, and specify certain components of a plan in the form of a safe harbor provision? Or, should the rule not specify required components of a plan and instead allow advisers to determine the appropriate components of their plans? Are there any components we should remove from the proposed list of required components? Are there any components we should add or expand upon? For example, with respect to a pre-arranged alternate physical location(s) of the adviser's office(s) and/or employees, should we require that an adviser's business continuity and transition plan include an alternate location at a specified distance away from its primary location? Should we require an adviser's communication plan to extend to investors in certain types of pooled investment vehicles? If so, which specific types of pooled investment vehicles and how should the term "investors" be defined for each type of pooled investment vehicle? Should we require an adviser to have policies and procedures that address the identification, assessment, and review of critical third-party vendors that the adviser arranges or oversees for its clients?
- Are there any components of the NASAA model rule or guidance, or other rules or guidance addressing BCPs, that we have not addressed in the proposed rule that we should address? Should advisers with certain types of clients, including for example advisers to registered investment companies or sponsors of wrap programs, be required to undergo additional obligations with regard to adopting and implementing a business continuity and transition plan? What additional steps should such advisers be required to take with respect

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[105] Some ISDA contracts include the default provision allowing for the counterparty to terminate a contract upon the change of advisers.

[106] Section 15(a) of the Investment Company Act states that "[i]t shall be unlawful for any person to serve or act as investment adviser of a registered investment company except pursuant to a written contact, which . . . has been approved by the vote of a majority of the outstanding securities of such registered company . . . ." Additionally, section 15(c) of the Investment Company Act states that "it shall be unlawful for any registered investment company having a board of directors to enter into . . . any contract or agreement, written or oral, whereby a person undertakes regularly to serve or act as investment adviser of . . . such company, unless the terms of such contract or agreement and any renewal thereof have been approved by the vote of a majority of directors, who are not parties to such contract or agreement or interested persons of any such party, cast in person at a meeting called for the purpose of voting on such approval." *But see, e.g.,* rule 15a–4 under the Investment Company Act (allowing funds, in certain circumstances, to enter into interim advisory agreements without an in-person board meeting and without the fund's shareholders first approving the agreement); *see generally* JP Morgan Chase/Bear Stearns Asset Management, SEC Staff No-Action Letter (July 14, 2008) (providing staff no-action relief following the US-government-brokered emergency sale of Bear Stearns Companies Inc. to JP Morgan Chase & Co., to allow Bear Stearns Asset Management to continue to serve as investment adviser to its funds without prior in-person approval by the funds' board of directors due to the extraordinary circumstances surrounding the sale of its parent company).

[107] Section 205(a)(2) of the Advisers Act requires any investment advisory contract to contain a provision indicating "that no assignment of such contract shall be made by the investment adviser without the consent of the other party to the contract." Section 202(a)(1) of the Advisers Act defines "assignment," for purposes of the Advisers Act, to include "any direct or indirect transfer or hypothecation of an investment advisory contract by the assignor or of a controlling block of the assignor's outstanding voting securities by a security holder of the assignor. . . ."

[108] *See, e.g.,* Third Avenue Trust and Third Avenue Management LLC, Investment Company Act Rel. No. 31943 (Dec. 16, 2015) (Notice and Temporary Order) (permitting the suspension of the right of redemption of Third Avenue Trust's outstanding redeemable securities).

[109] For example, as of January 4, 2016, the number of foreign registrations of SEC-registered investment advisers was 2,279, representing 1,051 SEC-registered investment advisers, some of which were registered in multiple foreign jurisdictions. Additionally, there were 780 foreign investment advisers registered with the Commission as of that same date. Based on data from IARD.

[110] When evaluating options for Long-Term Capital Management, L.P. during its collapse, the effects of the fund filing for bankruptcy were not clear because the fund was managed by an advisory entity domiciled in Delaware and located in Connecticut, while the fund itself was domiciled in the Cayman Islands, where the rights of its counterparties to liquidate collateral under the U.S. Bankruptcy Code would have been delayed because the fund would have likely had to seek bankruptcy protection in the Cayman Islands courts, under Cayman law. *See* Report of The President's Working Group on Financial Markets, Hedge Funds, Leverage, and the Lessons of Long-Term Capital Management (Apr. 28, 1999), *available at https://www.treasury.gov/resource-center/fin-mkts/Documents/hedgfund.pdf.*

[111] We note that, in certain circumstances, an adviser is required to "disclose any financial condition that is reasonably likely to impair [the adviser's] ability to meet contractual commitments to clients." *See* Form ADV, Part 2, Item 18.

[112] When considering any material financial resources available to it, the adviser also could identify any insurance coverage.

to such clients and/or such clients' service providers?

- Are each of the proposed components of a business continuity and transition plan clear or should we provide additional information and/or definitions for any of the components? If so, what additional information or definitions are needed? For example, should we provide a definition of "significant business disruption," "unable to continue providing investment advisory services," or "pooled investment vehicle"? Alternatively, should we require investment advisers to define certain terms, like "significant business disruption" or "unable to continue providing investment advisory services," within their plans?
- Should all advisers be required to include each of the proposed components in a business continuity and transition plan or should certain advisers be exempt from including certain components? If certain advisers should be exempt, why? For example, should only certain advisers be required to adopt and implement the transition plan component of the proposed rule or is there a subset of investment advisers with operations so limited that the adoption and implementation of a transition plan (or certain components of the transition plan requirement) would not be beneficial? If so, what criteria could be used to identify this subset of advisers? Are there alternative or streamlined measures that these advisers could take to facilitate an orderly transition in the event of a significant disruption to the adviser's operations? If these advisers did not have transition plans, should they be required to disclose the absence of such plan?
- With respect to each of the proposed components of a business continuity and transition plan, we have provided information as to the items and/or actions that we believe generally should be encompassed within a particular component. Is there additional information that we should provide, or any information that we should exclude or modify, regarding any of the proposed components of a plan? Alternatively, instead of permitting advisers the flexibility to draft their plans based on the complexity of their businesses, should we require advisers to address each component in a prescriptive manner by requiring specific mechanisms for addressing particular risks?
- Should we adopt a more prescriptive rule that calls for a more specific transition plan similar to the "Living Wills" required by the Federal Reserve Board and the FDIC for large banks and systemically important non-bank entities?[113] If so why, and what specifically should the rule require?
- As part of the proposed rule, should we require advisers to provide disclosure to their clients about their business continuity and transition plans? If so, what should be the format of such disclosure (*e.g.*, summary of plan, copy of plan)? When or how frequently should this disclosure be provided? Should we require advisers to disclose to their clients incidents where they relied on or activated their business continuity and transition plans? If so, what should be the format of such disclosure? What types of incidents should be disclosed or not disclosed?
- As part of the proposed rule, should we require advisers to report to the Commission incidents where they rely on their business continuity and transition plans? If so, under what circumstances should advisers be required to report to the Commission and how should advisers report this information? When should the required reporting occur?
- Should we require advisers to file their business continuity and transition plans, or a summary thereof, with the Commission? Should these filings be made available to the public? Why or why not? Are business continuity and transition plans considered proprietary to an adviser such that disclosing its plan to the public (either through a Commission filing or through disclosure to a client) creates additional risk exposure to the adviser?

2. Annual Review

Under the proposed rule, each adviser would be required to review the adequacy of its business continuity and transition plan and the effectiveness of its implementation at least annually. The review generally should consider any changes to the adviser's products, services, operations, critical third-party service providers, structure, business activities, client types, location, and any regulatory changes that might suggest a need to revise the plan.

The annual review provision is designed to require advisers to evaluate periodically whether their business continuity and transition plans continue to, or would, work as designed and whether changes are needed for continued adequacy and effectiveness. For example, the review generally should include an analysis of whether a business continuity and transition plan adequately protects client interests from being placed at risk and to mitigate such risks in the event the adviser experiences a significant disruption in its operations. In addition, annual reviews generally should address weaknesses an adviser may have identified in any testing it has done or assessments that have been performed to address the adequacy and effectiveness of its business continuity and transition plan, as well as any lessons learned if an event required the plan to be carried out during the previous year, including any changes made or contemplated as a result of the event.

- Should we require that business continuity and transition plans be reviewed at least annually, as proposed? Should we expressly require reviews of business continuity and transition plans to be documented in writing? Should we require more frequent or less frequent review of business continuity and transition plans? In addition to annual review, should we require that advisers review their plans when specific events occur? For example, should we require plans be reviewed when an adviser has an event that causes it to rely on its plan? Should we require plans be reviewed based on changes to the adviser's operations or processes, changes in the ownership or business structure of the adviser, compliance or audit recommendations, lessons learned from testing or disruption events, and/or regulatory developments?
- Should we require advisers to report to the Commission regarding the annual review of their business continuity and transition plans? If so, what should be the format of the report?
- Should we explicitly require advisers to annually review the business continuity and transition plans of their third-party service providers that provide critical services to the adviser and its clients? If so, how should these reviews be conducted? What types of documentation could be requested to perform these reviews?
- Should we specifically require advisers to periodically test their business continuity and transition plans or certain material components thereof to assess whether the plans are adequate and effective? If so, how should such testing be conducted? What should be

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[113] These resolution plans require, among other things: (1) Information regarding the manner and extent to which any insured depository institution affiliated with the company is adequately protected from risks arising from the activities of any nonbank subsidiaries of the company; (2) full descriptions of the ownership structure, assets, liabilities, and contractual obligations of the company; and (3) identification of the cross-guarantees tied to different securities, identification of the major counterparties, and a process for determining to whom the collateral of the company is pledged. *See* Resolution Plans, *supra* note 40.

included in the scope of such review? How often should such testing be required?

3. Recordkeeping

The proposed amendments would require SEC-registered advisers to maintain copies of all written business continuity and transition plans that are in effect or were in effect at any time during the last five years after the compliance date. We are requiring an adviser to maintain a copy of the plan currently in effect because we believe that it is important that advisers have easy access to necessary information during periods of stress. The proposed rule would also require that advisers keep any records documenting their annual review.[114] Our rules permit advisers to maintain these records electronically.[115] These proposed new recordkeeping requirements will assist our examination staff in evaluating an adviser's compliance with the new rule, including evaluating whether the adviser's business continuity and transition plan includes all required components. These proposed requirements track the recordkeeping requirements under rule 204–2 regarding an adviser's compliance policies and procedures.

We request comment on the proposed recordkeeping requirements.

- Should we require advisers to maintain copies of their business continuity and transition plans that are in effect or were in effect at any time during the last five years, as proposed? If not, what, if any, recordkeeping requirements should we adopt with respect to business continuity and transition plans? Is five years an appropriate retention period? Should it be longer or shorter? Why?
- Should we require advisers to keep any records documenting their annual review of their business continuity and transition plans, as proposed?

II. Economic Analysis

A. Introduction

The Commission is sensitive to the potential economic effects of proposed rule 206(4)–4 and the proposed amendments to rule 204–2. These effects include benefits and costs to SEC-registered advisers, clients, and fund investors as well as broader implications for market efficiency, competition, and capital formation.[116] The economic effects of the proposed rule are discussed below in the context of the primary goals of the proposed regulation.

We have sought, where possible, to quantify the costs, benefits, and effects on efficiency, competition, and capital formation expected to result from the proposed regulations. However, as discussed below, in certain cases, we were unable to quantify the economic effects because we lack the information necessary to provide reasonable estimates, such as the extent to which some advisers already have business continuity or transition plans that would satisfy some or all of the requirements of the proposed rule, the likelihood of business disruptions, and the share of costs arising from the proposed rule that advisers will pass through to its clients. Therefore, some of the discussions below are qualitative in nature.

Under the proposed rule, the content of an SEC-registered adviser's business continuity and transition plan shall be based upon risks associated with the adviser's operations and shall include policies and procedures designed to minimize material service disruptions, including policies and procedures that address the following: (1) Maintenance of critical operations and systems, and the protection, backup, and recovery of data; (2) pre-arranged alternate physical location(s) of the adviser's office(s) and/or employees; (3) communications with clients, employees, service providers, and regulators; (4) identification and assessment of third-party services critical to the operation of the adviser; and (5) plan of transition that accounts for the possible winding down of the adviser's business or the transition of the adviser's business to others in the event the adviser is unable to continue providing advisory services. The proposed rule also requires that each SEC-registered adviser review, no less frequently than annually, the adequacy of its business continuity and transition plan and the effectiveness of its implementation. In addition, the proposed amendments to rule 204–2 under the Advisers Act requires these advisers to make and keep records of all business continuity and transition plans that are in effect or were in effect at any time within the past five years.

The goal of these proposals is to require that all advisers have sufficiently robust plans to mitigate the potential adverse effects of significant business disruptions or transition events. Specifically, the proposed rule requires SEC-registered advisers to adopt plans reasonably designed to protect clients and fund investors from the risk that, in the wake of a significant business disruption or transition event, advisers are unable to provide services and continue operations. Such disruptions may put clients' and investors' interests at risk if, for example, an adviser lacks the ability to make trades in a portfolio, is unable to receive or implement directions from clients, or its clients are unable to access their assets or accounts.

Because clients and investors should be averse to these outcomes, one might expect all advisers to already have plans in place to minimize the risks posed by significant business disruptions or business transitions without being legally required to do so. It appears, however, that, in the context of business continuity and transition plans, market pressures do not fully align the interests of all advisers with those of their clients and fund investors, as staff has observed that some advisers have adopted plans that may not be sufficiently robust in light of the operational and other risks specific to their businesses. Our staff's observations that business continuity and transition plans are not uniformly robust suggest that both advisers and their clients may not fully take into account, or internalize, the potential benefits of comprehensive business continuity and transition plans as well as the potential costs of operating without them.

There are several possible reasons for this misalignment. As an initial matter, the types of business disruptions addressed by this proposal are infrequent, and are not necessarily publicly observable when they do occur; this may make it difficult for market participants to fully internalize the ramifications of those events. For example, an adviser that underestimates the likelihood of a significant disruption or the harm it could cause to the viability of its business may not believe the cost of a more robust business continuity plan is justified. Furthermore, because many advisers may have never experienced a significant business disruption, they might not properly assess whether their existing plans are sufficiently robust. And while some clients and investors may recognize the benefits of business continuity planning and demand it of their advisers, others may not fully understand these benefits due to the rarity of significant disruptions.

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[114] Pursuant to rule 204–2(e)(1) of the Advisers Act, advisers would have to maintain any records documenting their annual review in an easily accessible place for at least five years after the end of the fiscal year in which the review was conducted, the first two years in an appropriate office of the investment adviser.

[115] *See* rule 204–2(g) under the Advisers Act.

[116] The Commission recognizes that there are other entities that could be affected by the proposed rule. For example, vendors might have to adapt to meet the new demands of their clients under the proposed rule and that could change the nature of those product/service markets, which in turn could have further economic effects on advisers and their clients and investors. However, the effects of the rulemaking on such entities are uncertain and difficult to predict given they are not direct effects of the proposed rule.

In addition, staff observations resulting from specific SEC examinations are generally not made public, so any examination findings identified with respect to one adviser's plan will generally provide no guidance to other advisers, or to their clients and investors, as to what robust plans might contain. Although Commission staff has published alerts identifying overall observed weaknesses in advisers' business continuity plans, those alerts provide aggregated, non-specific information that may not inform advisers or their clients and investors of the expected content of robust plans.[117] Moreover, it is possible that some advisers may not review those alerts and therefore do not adjust their business continuity plans in response to the identified strengths and weaknesses; similarly, many clients and investors, particularly smaller or retail investors, may not review the alerts and thus do not exert pressure on their advisers to address in their own plans the general weaknesses identified by the Commission.[118]

Furthermore, advisers generally do not make their business continuity plans (or transition plans) public, though based on Commission staff's experience, we understand that most will provide a summary of those plans or other information related to their operational and other risks to clients and investors upon request. Clients and investors that request, review, and comment on these plans are more likely to exert some degree of pressure on their advisers regarding the content of their plans, thereby leading to more robust plans. Thus, the composition of an adviser's client base may impact the current state of its business continuity and transition plans and may lead to the heterogeneity in the quality of such plans that our staff has observed across advisers. The Commission believes, based on staff experience, that larger institutional clients and investors, compared to smaller or retail clients and investors, are more likely to engage in extensive due diligence processes that involve such review of existing plans. The content of business continuity and transition plans for advisers with larger institutional clients and investors may therefore be more likely to reflect such client or investor input than plans of advisers with only smaller, retail clients or investors. In addition, because plans are not generally public, advisers cannot compare their own plans with those of other advisers to assess the relative strengths and weaknesses of their plans and therefore do not have the opportunity to craft or revise their own plans with the knowledge of how others in the industry are addressing the same issues. These factors, combined with the absence of any specified requirements for components of business continuity plans (or transition plans) in existing regulation, may have contributed to staff's observations that such plans are not uniformly robust.

Advisers also may not fully internalize the benefits of transition planning. For example, it is possible that advisers do not necessarily have adequate incentives to ensure that a business transition takes into account all of the various components of a robust plan set forth in the proposed rule, given that an adviser no longer receives fees after that transition. In addition, transition events, like business disruptions, are relatively rare; accordingly, advisers may not properly assess the likelihood of such events, the potential consequences of failing to adequately prepare, or the benefits of ensuring a smooth transition.

To address the issues identified above, the proposed rule requires advisers to assess the operational and other risks associated with its business operations and identifies components that must be addressed in business continuity and transition plans. The rule aims to address the lack of uniformly robust plans previously observed by staff and requires each SEC-registered investment adviser to adopt and implement a written business continuity and transition plan based upon the risks associated with the adviser's operations.

B. Economic Baseline

The investment adviser regulatory regime currently in effect serves as the economic baseline against which the benefits and costs, as well as the impact on efficiency, competition, and capital formation of the proposed rule are discussed. As of January 4, 2016, there were 11,956 SEC-registered investment advisers with approximately $67 trillion in regulatory assets under management. In this market, which has been described as being highly competitive,[119] advisers are likely to compete on, among other things, fees charged to clients, returns or performance, and the level of services provided to meet client needs.

The proposed rule would affect all SEC-registered investment advisers, as well as each adviser's clients (including registered funds, private funds, and individual separately managed accounts) and the investors in fund clients. Currently, Commission guidance indicates that an SEC-registered adviser's compliance policies and procedures should include business continuity planning to the extent it is relevant to the adviser's business. The content of those BCPs, however, is not addressed by current Commission rules, and may not specifically include policies and procedures regarding business transitions.

As noted previously, our staff has noticed variation in the business continuity and/or transition plans that they have seen during examinations. Some advisers, pursuant to the Compliance Program Rule or as a prudent business practice, have adopted plans which may be consistent with the new requirements being proposed, while others have not. Accordingly, the benefits and costs to a given adviser, client, or fund investor will depend on the current state of the adviser's business continuity and transition plan.

C. Benefits and Costs and Effects on Efficiency, Competition, and Capital Formation

Taking into account the goals of the proposed rule and the economic baseline, as discussed above, this section explores the benefits and costs of the proposed rule, as well as the potential effects of the proposed rule on efficiency, competition, and capital formation.

1. Benefits

Clients and investors in funds managed by SEC-registered advisers, advisers themselves, and the financial markets as a whole may benefit from the proposed rule. In general, we cannot quantify the total benefits to the affected parties because we lack data on certain factors relevant to such an analysis, such as investor preferences and the likelihood of business disruptions. For example, without knowing how risk averse clients are to investing via advisers without robust BCPs, we cannot quantify the benefits they might derive from improvements in those BCPs. Similarly, it is difficult to estimate the probability of the types of business disruptions addressed by the proposed rule, which precludes precisely estimating the ex-ante costs of inadequate plans under the economic baseline. However, we discuss the expected benefits qualitatively below.

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[117] *See, e.g.*, NEP Risk Alert, *supra* note 30.

[118] We note that, based on staff experience, large institutional clients often have rigorous due diligence processes that evaluate an adviser's operational and other risks, while smaller retail clients may not engage in such a thorough review of operational and other risks.

[119] *See supra* section I.A and note 7.

We anticipate that clients and investors in funds managed by registered advisers will benefit from the proposed rule. Requiring SEC-registered advisers to adopt and implement business continuity and transition plans will likely reduce the risk that investors and advisory clients will be harmed or affected in the event a business continuity or transition issue actually occurs. For example, advanced planning to address issues in the event of a disruption may reduce the risk that advisory accounts might be left unmanaged or that clients do not have access to their funds during an adviser's business interruption or transition, or at least shortens the time of such a disruption. As discussed above, whether it is due to prudent business practices or adherence to the Commission guidance in the Compliance Program Rule, some advisers may already have robust business continuity and transition plans in place that are consistent with the new requirements being proposed. The incremental benefits of the proposed rule to those advisers' clients and investors would likely be less than the benefit to the clients and investors of an adviser without such strong operational controls.

The proposed rule will also benefit registered advisers by requiring their business continuity and transition plans to include policies and procedures that address certain specific components, which should help the advisers better prepare for significant disruptions in their operations. While Commission guidance indicates that an SEC-registered adviser's compliance policies and procedures should address BCPs to the extent that they are relevant to an adviser, the Commission has not previously specified what such a BCP should address. To the extent registered advisers have not already adopted and implemented robust BCPs that are consistent with the new requirements being proposed, requiring them to review the risks associated with their operations and plan for significant business disruptions or transitions should encourage them to enhance their ongoing efforts to mitigate risks attendant with their operations and business practices and may help them be better prepared to address business continuity and transition events if and when they occur.

Finally, the proposed rule and the planning it requires of advisers could have ancillary benefits for the broader financial markets. For example, consider an adviser with significant assets under management who trades actively enough to be considered a liquidity provider in a particular market. If this adviser were to suffer a significant business disruption event that prevented it from participating in that market for several days, then the liquidity of the market could be negatively affected.[120] While a business continuity and transition plan would not be able to completely prevent such a disruption, it may decrease the adviser's recovery time and hence the disruption's impact on the market.

2. Costs

As with the benefits, costs of the proposed rule will be shared by advisers and their clients and fund investors. Generally, advisers will incur the direct costs associated with developing and maintaining robust business continuity and transition plans, though some of those costs may ultimately be passed through to their clients and fund investors. These costs are discussed in more detail below.

a. Costs to Advisers

Proposed rule 206(4)–4 likely will result in an SEC-registered adviser incurring one-time and ongoing operational costs, described in detail below, to adopt and implement a business continuity and transition plan that is reasonably designed to address the operational and other risks related to a significant disruption in the adviser's operations. As an initial matter, it is difficult to determine the estimated costs for advisers with precision because of the variation in existing BCPs and the extent to which such plans will need to be revised to be compliant with the proposed rule. Because Commission guidance indicates that SEC-registered advisers' compliance policies and procedures should address BCPs to the extent that they are relevant to an adviser, the nature of an adviser's existing BCP will also greatly affect the initial costs the adviser would expend to comply with the proposed rule. Advisers whose current BCPs are closely aligned with the requirements of the proposed rule would likely incur lower initial compliance costs relative to advisers whose current BCPs are not closely aligned with the rule's requirements, while all advisers would incur ongoing costs pertaining to the annual review and recordkeeping components of the proposed rule.[121]

In addition, because the proposed rule requires an SEC-registered adviser's plan to be based on the particular risks attendant to that adviser's operations, the initial and ongoing costs imposed by the rule would vary significantly among firms depending on the complexity of the adviser's operations. A number of factors pertaining to an adviser's business model can affect the complexity of the adviser's operations. Those factors include the adviser's assets under management, number of employees, number of offices, number and types of clients (*e.g.*, high net worth individuals, private funds, or registered investment companies), types of advisory activities, other business activities or lines of business which may affect the adviser's advisory business, types of investment strategies pursued, and the extent of reliance on service providers (in-sourced vs. out-sourced models). The flexibility of the proposed rule should allow advisers to tailor their business continuity and transition plans to the specific risks their businesses face at the minimum possible cost.

The Commission believes that certain of the above factors may be correlated with the adviser's amount of assets under management. For example, an adviser with a large amount of assets under management is more likely to have more employees, multiple locations, offices, numbers and types of clients, and types of business activities than an adviser with fewer assets under management.[122] Accordingly, we believe that advisers with larger amounts of assets under management are generally more likely to have more complex business operations and may therefore need to expend more resources on adopting, implementing, and maintaining a business continuity and transition plan than advisers with fewer assets under management.[123]

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[120] *See, e.g.*, George O. Aragon & Philip E. Strahan, *Hedge funds as liquidity providers: Evidence from the Lehman bankruptcy*, J. Financ. Econ., Vol. 103, Issue 3 (Mar. 2012) at 570–587 (concluding that "the market liquidity of stocks held by Lehman's hedge-fund clients fell more during the [2008 financial] crises than otherwise similar stocks not held by these funds.")

[121] The costs estimates provided in this section include total costs for developing and maintaining both business continuity plans and transition plans. We recognize, however, that the portion of these costs attributable to business continuity plans will likely be greater than that attributable to the transition plans, as business continuity plans generally contemplate acquiring and maintaining, for example, more infrastructure, such as secondary storage capabilities, than transition plans and is more likely to involve retaining third-party vendors to assist with the development or maintaining of that infrastructure. Accordingly, the current state of an adviser's business continuity plans may have more effect on the costs to individual advisers than the current state of the adviser's transition plans.

[122] With regard to employee size, SEC-registered advisers with less than $100 million in assets under management have an average of 28 employees and a median of 4 employees, while SEC-registered advisers with over $1 billion in assets under management have an average of 180 employees and a median of 31 employees. Based on data from IARD as of January 4, 2016. With regard to the number of offices maintained by advisers, only 23% of SEC-registered advisers with less than $100 million in assets under management maintain more than one office, while 47% of SEC-registered advisers with over $1 billion in assets maintain one or more offices and 11% of these larger advisers maintain 5 or more offices. Based on data from IARD as of January 4, 2016.

i. One-time Costs

As noted above, the one-time costs associated with developing and implementing the policies and procedures associated with a business continuity and transition plan will vary significantly among firms depending on the nature and complexity of the adviser's operations and the current state of their systems and processes. Under the proposed rule, SEC-registered advisers need only take into account the risks associated with their particular operations. For example, smaller advisers that do not have a large number or different types of clients or do not maintain numerous offices with numerous employees may not need complex systems if their operations result in risks that are easy to address. On the other hand, a larger adviser with a large number and diverse set of clients, including large registered investment companies, with global offices and thousands of employees may need more complicated and expensive systems and technology. To the extent that adviser size does correlate with operational complexity, SEC examination staff has observed that larger advisers have typically already devoted significant resources to establish systems or technological solutions that address operational and other risks related to business continuity.

Based on our staff's experience, we generally estimate that the one-time costs necessary to adopt and implement a business continuity and transition plan would range from approximately $30,000 to $1.5 million[124] per SEC-registered adviser, depending on the facts and circumstances of a particular adviser's operations and the adequacy of its existing plan. These estimated costs include internal and external costs, explained in more detail below, attributable to the following activities: (1) Mostly internal costs associated with developing policies and procedures related to each required component of the business continuity and transition plan; and (2) external costs associated with integrating and implementing the policies and procedures as described above (including establishing or upgrading current systems and processes to comply with the proposed rule).

We anticipate that developing policies and procedures designed to minimize material service disruptions, including those related to each required component of the business continuity and transition plan will largely be done internally because it will require an evaluation of the adviser's business operations most suited to be conducted by in-house employees familiar with the intricacies of the business operations. These costs are quantified and discussed in more detail in the PRA section below, but in summary, we estimate that this initial one-time cost will range from approximately $17,000 to $170,000, depending on the facts and circumstances of a particular adviser's operations and the comprehensiveness of their existing plan.[125]

With respect to integration and implementation of the policies and procedures described above, an adviser may incur external costs to upgrade systems and processes. The external costs incurred by an adviser to meet the required components of the proposed rule would be directly affected by the current state of the adviser's existing systems and processes. For example, the proposed rule specifies that an adviser must address the maintenance of critical operations and systems and the protection, backup, and recovery of data. While our staff observes that most advisers already have systems in place to address the protection, backup, and recovery of data, an adviser that does not already have a system in place would incur the costs associated with implementing an operational solution to protecting its data.[126] Also, the proposed rule specifies that an adviser's plan include a pre-arranged alternative physical location of its office(s) and/or employees. While many advisers already have back-up locations identified as a co-location in times of business disruptions and equipped their employees to telework if they are unable to travel to the primary office location, an adviser that has not adequately addressed this component of the proposed rule would incur costs to do so in light of the proposed rule.[127]

The proposed rule also requires that the adviser address how it will communicate with clients, employees, service providers, and regulators in the event of a business disruption. While advisers have communication tools as part of its general business operations that enable it to communicate to its stakeholders (*i.e.*, email, phone, etc.), some advisers may have formal, more sophisticated communication infrastructure already in place.[128] The proposed rule further requires advisers to engage in an assessment of critical third-party vendors, including assessing how service providers will maintain business continuity when faced with significant business disruption. While some advisers currently have robust vendor management programs that take steps to evaluate the resiliency of vendors, including reviewing information regarding their BCPs, due diligence questionnaires or assurance control reports from an independent party, and onsite visits, some advisers do not and will need to incur costs to enhance their review of critical third-party vendors.[129]

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[123] There are notable exceptions: for example, a small adviser with a technology intensive investment strategy may nevertheless have a complex operational risk profile, which could require a more complex business continuity and transition plan.

[124] These estimates are based on the aggregated low-end of the range and the high-end of the range, respectively, of mostly internal costs detailed in the PRA section below and the external costs associated with integrating and implementing the plan. Specifically, these estimates are based on the following calculations, which are described in greater detail in notes 125 through 129:

$12,515 low-end estimated internal cost to adviser for developing policies and procedures + $4,000 low-end estimated cost to adviser for external professional fees for developing policies and procedures + $1,000 low-end estimated cost to adviser for maintenance of critical operations and systems and the protection, backup and recovery of data + $5,000 low-end estimated cost to adviser for a prearranged alternative physical location + $0 low-end estimated cost to adviser for a plan of communication + $5,000 low-end estimated cost for third-party oversight = $27,515.

$147,310 high-end estimated internal cost to adviser for developing policies and procedures + $20,000 high-end estimated cost to adviser for external professional fees for developing policies and procedures + $750,000 high-end estimated cost to adviser for maintenance of critical operations and systems and the protection, backup and recovery of data + $500,000 high-end estimated cost to adviser for a prearranged alternative physical location + $5,000 high-end estimated cost to adviser for a plan of communication + $50,000 high-end estimated cost for third-party oversight = $1,472,310.

See infra, notes 125 through 129.

[125] *See infra* section III.A.1. This estimate is based on the following calculations: $12,515 internal cost to representative smaller adviser + $4,000 in external professional fees for representative smaller adviser = $16,515. $147,310 internal cost to representative larger adviser + $20,000 in external professional fees for representative larger adviser = $167,310.

[126] We estimate an adviser could spend between $1,000 and $750,000 to address the maintenance of critical operations and systems, and the protection, backup and recovery of data. The wide range is attributable to the varying methods in which advisers may address this component of the proposed rule. For example, smaller advisers may address data backup and recovery by outsourcing storage to a service provider through cloud software, while a large adviser dealing with large amounts of data may find it more cost effective to purchase data servers dedicated to the adviser.

[127] We estimate that an adviser could spend between $5,000 and $500,000 to address having a prearranged alternative physical location. The wide range is attributable to the varying methods in which advisers may address this component of the proposed rule. For example, a smaller adviser with minimal employees may be able to function by enabling its employees to telework and access the adviser's systems remotely instead of requiring formal meeting space. Larger advisers with many employees, on the other hand, may need to rent office space on a temporary basis or establish co-locations where employees necessary to the operations of an adviser may congregate.

[128] We estimate that an adviser could spend between almost nothing to up to $5,000 to address having a plan of communication with its stakeholders. The wide range is attributable to the varying methods in which advisers may address this component of the proposed rule. For example, a small adviser with minimal employees could manually email or telephone its stakeholders,

Aggregating our estimates for the various components of the rule, we estimate that SEC-registered advisers may spend between approximately $11,000 and $1.3 million in additional, initial costs to upgrade systems and processes to comply with the proposed rule depending on the complexity of their operations and the current state of their systems and processes, as described above.[130]

ii. Ongoing Costs

In addition to the one-time initial costs described above, each registered adviser would also incur ongoing costs as a result of the proposed rule related to the adviser's review of the adequacy of its business continuity and transition plan and the effectiveness of its implementation. This would involve internal costs associated with updating policies and procedures to reflect changes in an adviser's operational risk profile and costs of compliance and reporting associated with maintaining the plan, but would also include external costs associated with maintaining and upgrading systems, maintaining alternate work locations, and responding to regulatory changes that require revision of the adviser's business continuity and transition plan.[131] As discussed in the PRA section below, based on staff experience, we estimate that each adviser, in addition to the initial costs described above, would incur ongoing plan-related cost of approximately 25% of the adviser's initial costs in adopting and implementing a business continuity and transition plan. Accordingly, we estimate that an SEC-registered adviser would incur ongoing annual costs associated with the proposed rule that would range from $7,500 to $375,000.[132]

In addition, the proposed amendments to rule 204–2 would require registered advisers to maintain records related to the current plan and any plan in effect in the previous five years, as well as any records documenting the annual review of the plan required by the rule. As described in more detail in the PRA section below, we estimate that such advisers will spend approximately $150 each year on an ongoing basis to meet this requirement.

b. Costs to Clients and Investors

Some of the costs incurred by advisers as a result of the proposed rule may ultimately be passed on from advisers to clients and fund investors through higher fees. The extent to which costs are transferred to clients and investors depends on several factors, including the supply and demand for adviser services. On the demand side, the extent to which clients and investors respond to fee changes is a function of how highly they value a given adviser's services; the proposed rule may increase this valuation if investors value business continuity and transition plans and hence increase the demand for adviser services at a given fee, but the exact nature of this potential shift and its impact on fees is unknown.[133] On the supply side, if advisers take investor fee sensitivity into account, under many plausible competition scenarios in an adviser's market segment, it is likely at least some of the cost increases of the proposed rule will be passed on to clients and investors. However, if advisers incur costs associated with changing fees, advisers may not pass on the costs of the proposed rules until they cross some significant threshold. Since we do not have data or other information concerning individual investor fee sensitivities, how advisers take these into account, or the extent to which advisers prefer to keep fees constant, the potential shift in the supply of advisory service and its impact on fees is unknown.

3. Effects on Efficiency, Competition, and Capital Formation

The Commission has also considered the effects of the proposed rules on efficiency, competition, and capital formation. With respect to efficiency, to the extent that a disruption were to prevent an adviser from executing trades for several days, investors would be unable to make any changes in their investment choices, leading to a potentially inefficient allocation of their capital during this period. To the extent that the proposed rules decrease the recovery time of a disruption for an adviser that many market participants are relying on when conducting their business, they could promote efficient pricing of risk and thus efficient capital allocation during such an event.

The proposed rule also could affect competition in the advisory industry. As discussed above, the costs of adopting plans that meet the requirements of the proposed rule will vary depending on an adviser's operations and the extent to which they have already implemented business continuity and transition plans consistent with the rule. To the extent that, in a given market segment, advisers with high adoption costs compete for clients and investors against advisers with low adoption costs, the proposed rule will disproportionally affect the high adoption cost advisers. If some of these advisers are only marginally

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whereas a large adviser with many employees or clients could choose to use an automated system to trigger a pre-programmed communication plan.

[129] We estimate that an adviser could spend between $5,000 and $50,000 to address the requirement for third-party oversight. The wide range is attributable to the varying methods in which advisers may address this component of the proposed rule. As discussed in section I, many advisers may choose to use in-house personnel to conduct due diligence of critical service providers, while others may choose to pay others to conduct such due diligence on their behalf.

[130] These estimates are based on the aggregated low-end of the range and the high-end of the range, respectively, of mostly internal costs detailed in the PRA section below and the external costs associated with integrating and implementing the plan. Specifically, these estimates are based on the following calculations:

$1,000 low-end estimated cost to adviser for maintenance of critical operations and systems and the protection, backup and recovery of data + $5,000 low-end estimated cost to adviser for a prearranged alternative physical location + $0 low-end estimated cost to adviser for a plan of communication + $5,000 low-end estimated cost for third-party oversight = $11,000.

$750,000 high-end estimated cost to adviser for maintenance of critical operations and systems and the protection, backup and recovery of data + $500,000 high-end estimated cost to adviser for a prearranged alternative physical location + $5,000 high-end estimated cost to adviser for a plan of communication + $50,000 high-end estimated cost for third-party oversight = $1,305,000.

See supra, notes 125 through 129.

These estimates include the assumption that large advisers will incur more costs than smaller advisers based on their operational risk profile. Because these estimates do not take into account our staff observations that larger advisers generally already have more robust business continuity plans in place compared to smaller advisers, we believe our estimates may overstate the costs to be incurred by advisers.

[131] *See supra* section I.C.2 for more details on annual review requirements.

[132] This estimate is based on the following calculations: .25 × $30,000 = $7,500 and .25 × $1.5 million = $375,000. *See supra* note 124 and accompanying text (discussing total initial costs ranging from approximately $30,000 to $1.5 million).

[133] *See, e.g.,* John Haslem, *Mutual Fund Heterogeneity and Fee Dispersion,* J. Wealth. Manag., Vol. 18, No. 1 (Summer 2015) at 41–48, who argues that because preferences differ across investors, fee sensitivity also varies across investors.

profitable, they may exit that market segment. Similarly, the proposed rule could, on the margin, raise the barrier to entry for an adviser that otherwise would have entered a given market segment. If the rule results in either adviser exits or increased barriers to entry, reduced competitive pressures could result in increased fees for clients and investors.

Finally, the proposed rule may have a small but positive impact on capital formation. Ex-ante, reducing risks to clients and investors associated with business disruptions and transition events could increase such clients' and investors' willingness to invest via advisers, which could be beneficial to capital formation if advisers are more skilled than those clients or investors at identifying sound investment opportunities. In addition, to the extent that the rules reduce any risk premium in assets associated with business disruptions and transition events as discussed above, more robust business continuity and transition plans could promote capital formation.

D. Reasonable Alternatives

In formulating our proposal, we have considered various reasonable alternatives to certain individual elements of proposed new rule 206(4)–4 and the proposed amendments to rule 204–2. Those alternatives are discussed below. We have also requested comments relating to certain specific aspects of these alternatives, as noted above.

1. Require Public Availability of Business Continuity and Transition Plans

First, the Commission could require that SEC-registered advisers publicly disclose a summary of the plans required by the proposed rule in their Form ADVs, and either additionally or as an alternative, provide their business continuity and transition plans to clients upon request. In addition, as an alternative to the recordkeeping requirement, we could require registered advisers to file their business continuity and transition plans (or a portion or summary thereof) with the Commission.

Disclosing the plans or a summary of those plans, and the operational and other risks addressed by such plans, could help investors evaluate and compare the operational and other risks associated with particular advisers. If investors could choose among advisers in part based on the level of operational and other risk advisers were willing to bear, advisers might be further incentivized to plan for business disruption events. However, we understand that such information could be considered proprietary by some advisers and the public disclosure of business continuity and transition plans may make advisers more vulnerable to attacks from third parties, such as cybersecurity attacks that target the contingency plans laid out in an adviser's business continuity and transition plan. Furthermore, advisers would incur additional monetary costs associated with the disclosure of the plans. Such costs associated would vary depending on the type of disclosure required (*e.g.,* filing with the Commission, publication on the adviser's Web site, making the plans available upon request, etc.) and whether the adviser currently makes its plans available to clients.

In addition, instead of requiring certain components for business continuity plans for all advisers, as in the proposed rule, the Commission could continue imposing only the obligation generally set forth as guidance under the Compliance Program Rule but require public disclosure of any business continuity plans adopted pursuant to that rule. As noted above, the proposed rule's enhanced requirements for business continuity plans impose costs compared to the existing baseline, depending on an adviser's current business continuity plans, so this alternative would avoid the costs associated with complying with the proposed rule. Still, advisers would incur other costs related to disclosure of the existing business continuity plans, as noted above, including the direct monetary costs of publishing or providing the plans, as well as indirect costs such as those associated with revealing the proprietary or sensitive business information identified above.

Further, as discussed above, the non-public nature of existing business continuity plans may be a contributing factor to the lack of uniformly robust plans observed by Commission examiners. However, given the other factors discussed above that may also contribute to the lack of sufficiently robust plans among all advisers, the Commission preliminarily believes that only requiring public disclosure of existing business continuity plans without specifying certain components that plans must contain may not fully address its concerns that all advisers have not established sufficiently robust business continuity plans. At the same time, the Commission preliminarily believes that requiring business plans to address the components identified in the proposed rule while not mandating that such plans also be publicly disclosed will result in more uniformly robust plans that address the Commission's concerns.

2. Require Business Continuity Plans and/or Transition Plans, But Do Not Specify Required Components

The Commission could also specifically require advisers to adopt business continuity plans and/or transition plans but be silent as to the required components that such plans must contain to address business disruptions and/or transition events.[134] The proposed rule requires advisers to adopt and implement a business continuity and transition plan with policies and procedures reasonably designed to address operational and other risks related to a significant disruption in an adviser's operations (including policies and procedures concerning business transition), while also identifying specific components that such a plan must address. If, as an alternative, the Commission required business continuity and transition plans but did not identify any specific components the plans must address, registered advisers would have complete flexibility in determining how to best prepare for and respond to business disruptions and transition events. For example, it is possible that certain required components for business continuity and transition plans identified in the proposed rule are less relevant to some advisers, but all advisers would be required to address each of the components under the proposed rule. In contrast, an alternative that did not require specific components be addressed would enable advisers to tailor the plans to their specific business needs, which could potentially result in cost and time-savings compared to the proposed approach.

However, based on the Commission's experience with not providing specific components a plan should address in the context of business disruptions, under rule 206(4)–7, the Commission is concerned that some registered advisers may not implement sufficiently robust plans to best protect the interests of their clients and investors during a business disruption or transition event if the Commission does not specify certain components. In contrast, the Commission preliminarily believes that the current proposed approach strikes an appropriate balance between specifying certain components of business continuity and transition planning that must be addressed while still providing advisers with flexibility in how to address each of those components and any other operational and other risks that may be relevant to the adviser's operations. In addition, the Commission preliminarily believes that advisers will achieve certain efficiencies in simultaneously addressing both business disruptions and transition events under the proposed approach, which may mitigate additional costs imposed by the proposed approach.

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[134] The Commission could take different approaches for business disruptions and transition events. For example, the Commission could either retain the currently proposed approach of specifying certain components for addressing business disruptions or impose more specific mechanisms for addressing certain risks associated with business disruptions, as explained below, while not specifying either the components or the specific mechanisms for addressing transition events.

3. Require Specific Mechanisms for Addressing Certain Risks in Every Plan

As discussed above, we are proposing a rule that requires SEC-registered advisers to address certain general components, but permits them the flexibility to draft their business continuity and transition plans based on the risks associated with their particular operations. We could alternatively include in the rule prescriptive requirements mandating precisely how registered advisers must address certain specified risks related to either business disruptions or transition events, or both.[135]

Specific, mandatory requirements could potentially reduce confusion as to exactly how these advisers are expected to address business disruptions and/or transition events. However, as discussed above, we recognize that advisers' business models and operations vary and that the manner in which each adviser's business continuity and transition plan addresses a required element will depend upon the nature and complexity of the adviser's business. Therefore, a prescriptive one-size-fits-all rule mandating how all advisers must address certain specified risks, including risks a particular business model and operation would not be exposed to, could be inefficient and cause some advisers to incur unnecessary costs by requiring them to address requirements that are not relevant to their specific business. In addition, a prescriptive rule provides less flexibility for registered advisers to address new issues as they arise, particularly concerning changes in technology, again potentially leading to inefficient constraints on how registered advisers prepare for and address various risks. Therefore, we preliminarily believe our proposed approach strikes an appropriate balance between requiring that each adviser have a business continuity and transition plan that addresses certain required components we believe will help SEC-registered advisers to appropriately plan for significant business disruptions and transition events while, at the same time, allowing each adviser the necessary flexibility in creating a business continuity and transition plan to take into account the adviser's own unique operations, the nature and complexity of its business, its clients, and its key personnel.

4. Vary the Requirements of the Proposed Rule for Different Subsets of Registered Advisers

Additionally, instead of requiring that all SEC-registered advisers adopt and implement the business continuity and transition plans with the same exact components, we could vary those requirements by adviser. For example, the Commission could provide that various requirements of the rule only apply to a subset of registered advisers (*e.g.,* advisers over a certain asset threshold, advisers that are engaged in activities that the Commission deems to be risky, advisers that are affiliated with other financial industry participants, such as broker-dealers or banks, etc.), or it could provide that certain advisers (such as smaller advisers) are exempted from the rule entirely. As we have discussed above, different types of advisers have different types of operational and other risks and it is possible that requiring every adviser to address each of the risks identified in the proposed rule, even those that may be less likely for certain advisers, could result in unnecessary costs for those advisers.

However, the overall purpose of the proposed rule is to provide enhanced protection to clients and investors by requiring all registered advisers to establish sufficiently robust plans, and tailoring the rule to require different components for different types of advisers may result in the interests of some clients and investors not being adequately protected. Specifically, it is possible that, when distinguishing different "types" of advisers, any boundaries drawn would be imperfect and any groups of advisers identified by such a rule would themselves not be homogenous, resulting in under or over-inclusive groups. This could result in some clients and investors not receiving adequate protections, while still imposing unnecessary costs on others. In contrast, the proposed rule allows advisers the flexibility to address each required component to the degree that reflects the nature of each particular adviser's business. Accordingly, the Commission believes that the proposed rule strikes an appropriate balance in providing that protection while minimizing the costs of compliance to advisers in ways that would not undermine the Commission's regulatory goals.

E. Request for Comment

We request comment on our assumptions regarding the costs and benefits of the proposed rule. We request comment on whether the proposed rule, if adopted, would impose a burden on competition. We also request comment on whether the proposed rule, if adopted, would promote efficiency, competition, and capital formation. Commenters are requested to provide empirical data to support their views. In addition to our general request for comment on the costs and benefits of the proposed amendments, we request the following specific comment on certain aspects of our economic analysis.

- To what extent would advisers and their clients and investors benefit from business continuity and transition plans that are required to contain certain specific components? Please explain.
- Would advisers, and their clients and investors, benefit more from requiring plans to address certain risks in a specified manner, rather than providing for flexibility as in the proposed rule?
- Do commenters expect that advisers would incur costs in addition to, or that differ from, the costs we outlined above for both one-time and ongoing costs? Please explain.
- Would any of the effects and costs of the proposed rule be large enough to affect the behavior of investment advisers or their clients? For example:
    - ○ Do commenters expect that some advisers may choose to exit the market rather than incur the costs associated with compliance? If so, what segment of the investment adviser market is this mostly likely to be seen in and how many exiting advisers should we expect? Please explain.
    - ○ Will the costs to clients, in the form of increased fees, result in some clients no longer employing the services of advisers? If so, what types of clients would be most likely to take such actions? Please explain.

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[135] As noted above, the Commission could vary its approach for business continuity and transition plans. Specifically, for both business continuity plans and transition plans, the Commission could either (1) retain the more flexible component-based approach currently proposed, (2) mandate specific requirements for addressing business disruptions/transition events, or (3) only require "reasonably designed" plans without specifying particular components.

- Do commenters believe that the alternatives the Commission considered are appropriate? Are there other reasonable alternatives that the Commission should consider? If so, please provide additional alternatives and how their costs and benefits would compare to the proposal.
- Do commenters believe that the analysis of the associated costs and benefits of the alternatives is accurate? If not, please provide more accurate costs and benefits, including any data or statistics that supports those costs and benefits.

III. Paperwork Reduction Act

The proposed rule and rule amendments under the Advisers Act contain "collections of information" within the meaning of the Paperwork Reduction Act of 1995 ("PRA").[136] The title for the new collection of information is "Rule 206(4)–4." In addition, the proposed amendments to rule 204–2 would impact the currently approved collection of information titled "Rule 204–2," under OMB control number 3235–0278. These collections of information are mandatory for all investment advisers registered with the Commission. The Commission is submitting these collections of information to the OMB for review in accordance with 44 U.S.C. 3507 (d) and 5 CFR 1320.11. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The collection of information under rule 206(4)–4 is designed to increase the likelihood that advisers are as prepared as possible to continue operations on an ongoing basis and to meet client expectations and legal obligations in the event of a significant disruption to their operations. The respondents are investment advisers registered with the Commission. Responses provided to the Commission in the context of its examination and oversight program are generally kept confidential.[137]

The collection of information under rule 204–2 is necessary for the Commission staff to use in its examination and oversight program. The respondents are investment advisers registered with us. Responses provided to the Commission in the context of its examination and oversight program are generally kept confidential.[138] The records that an adviser must keep in accordance with the proposed rule must be retained for at least five years.[139]

A. The Proposed Rules

1. Rule 206(4)–4

As discussed in section II, we estimate that each adviser would include one-time initial costs to adopt and implement a written business continuity and transition plan, as well as ongoing plan-related costs. There are currently approximately 11,956 investment advisers registered with us.[140] We estimate that advisers will spend between 50 to 500 hours to initially adopt and implement a business continuity and transition plan depending on the nature of an adviser's current business continuity plan and the complexity of its operations. This range is comprised of our estimates that a representative smaller adviser (defined in this PRA as advisers with less than $100 million in assets under management) would spend 50 hours on this initial effort at a cost of $12,515,[141] a representative mid-sized adviser (defined in this PRA as advisers with at least $100 million in assets under management but less than $1 billion) would spend 250 hours on this initial effort at a cost of $70,045,[142] and a representative larger adviser (defined in this PRA as advisers with at least $1 billion in assets under management) would spend 500 hours on this initial effort at a cost of $147,310.[143] As discussed in section II, exact costs for any given adviser would depend on the facts and circumstances of the adviser's operations and the comprehensiveness of its existing plan. Aggregating the estimates above for all advisers, however, yields a total industry-wide initial hourly burden of 3,404,600[144] (as monetized, is equivalent to a one-time aggregate burden of approximately $974.6 million).[145] Amortized over a three-year period, this would be an annual hourly burden of 95 per adviser[146] (as monetized, is equivalent to an annual amortized burden per adviser of $27,172).[147]

We also anticipate that some advisers may consult with outside legal counsel and/or other outside professionals to assist in drafting policies and procedures and/or to assist in evaluating particular components of a plan. We estimate that the costs associated with such an engagement would include fees for approximately 10 hours for smaller firms, 30 hours for a mid-sized firm, and 50 hours for a larger firm, at an average rate of $400 per hour (estimated hourly rate for outside legal services).[148] Consequently, for a smaller firm we estimate a total of $4,000 in outside fees for each smaller firm,[149] $12,000 for each medium firm,[150] and $20,000 for each larger firm.[151] Aggregating these estimates for all advisers, yields a total industry wide initial cost burden of $153.5 million attributable to engaging outside legal services for assistance in initially drafting and implementing the BCP.[152] Amortized over a three-year period, this would be an initial annual cost burden per adviser of $4,282.[153]

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[136] 44 U.S.C. 3501 through 3521.

[137] *See* section 210(b) of the Advisers Act.

[138] *See* section 210(b) of the Advisers Act.

[139] *See* proposed rule 204–2(a)(20).

[140] This is the number of investment advisers registered with us on our IARD System as of January 4, 2016.

[141] This estimate is based on the following calculations: 25 hours × $288 (hourly rate for a compliance manager) = $7,200; 20 hours × $127 (hourly rate for an operations specialist) = $2,540; 5 hours × $555 (hourly rate for a deputy general counsel) = $2,775. $7,200 + $2,540 + 2,775 = $12,515. The hourly wages used are from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified to account for an 1800-hour work-year and inflation (as of January 2016) and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[142] This estimate is based on the following calculations: 75 hours × $288 (hourly rate for a compliance manager) = $21,600; 60 hours × $127 (hourly rate for an operations specialist) = $7,620; 15 hours × $555 (hourly rate for a deputy general counsel) = $8,325; 50 hours × $264 (hourly rate for a senior systems analyst) = $13,200; 50 hours × $386 (hourly rate for an attorney) = $19,300. $21,600 + $7,620 + $8,325 + $13,200 + $19,300 = $70,045. The hourly wages used are from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified to account for an 1800-hour work-year and inflation (as of January 2016) and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[143] This estimate is based on the following calculations: 100 hours × $288 (hourly rate for a compliance manager) = $28,800; 80 hours × $127 (hourly rate for an operations specialist) = $10,160; 20 hours × $555 (hourly rate for a deputy general counsel) = $11,100; 65 hours × $264 (hourly rate for a senior systems analyst) = $17,160; 65 hours × $386 (hourly rate for an attorney) = $25,090; 30 hours × $410 (hourly rate for a computer operations department manager) = $12,300; 30 hours × $271 (hourly rate for a financial reporting manager) = $8,130; 40 hours × $340 (hourly rate for a senior operations manager) = $13,600; 30 hours × $255 (hourly rate for a senior business analyst) = $7,650; 40 hours × $333 (hourly rate for a senior risk management specialist) = $13,320. $28,800 + $10,160 + $11,100 + $17,160 + $25,090 + $12,300 + $8,130 + $13,600 + $7,650 + $13,320 = $147,310. The hourly wages used are from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified to account for an 1800-hour work-year and inflation (as of January 2016) and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[144] This estimate is based on the following calculations: (2,032 smaller advisers × 50 hours) + (6,636 mid-sized advisers × 250 hours) + (3,288 larger advisers × 500 hours) = 3,404,600 hours.

[145] This estimate is based on the following calculation: (2,032 smaller advisers × $12,515) + (6,636 mid-sized advisers × $70,045) + (3,288 larger advisers × $147,310) = $974.6 million.

[146] This estimate is based on the following calculations: 3,404,600 hours/3 years = 1,134,867 hours per year. 1,134,867 hours/11,956 advisers = 95 hours per year per adviser.

[147] This estimate is based on the following calculations: $974.6 million/3 years = $324.87 million per year. $324.87 million/11,956 advisers = $27,172 per year per adviser.

[148] We recognize that the costs of retaining outside professionals may vary depending on the nature of the professional services, but for purposes of this PRA analysis we estimate that such costs would be similar to the costs of outside legal services.

In addition to the initial burden, an adviser would incur ongoing, annual costs associated with its business continuity and transition plan, including the adviser annually reviewing the adequacy of its business continuity and transition plan and the effectiveness of its implementation. Based on staff experience, we estimate these ongoing costs would total approximately 25% of an adviser's initial costs. Accordingly, we estimate that a representative smaller adviser would spend 12.5 hours annually on this effort internally (as monetized, is equivalent to an annual burden of $3,129) while incurring outside costs of $1,000,[154] a representative mid-sized adviser would spend 62.5 hours annually on this effort internally (as monetized, is equivalent to an annual burden of $17,511) while incurring outside costs of $3,000,[155] and a representative larger adviser would spend 125 hours annually on this effort internally (as monetized, is equivalent to an annual burden of $36,828) while incurring outside costs of $5,000.[156] Aggregating the estimates above for all advisers yields a total industry-wide ongoing annual burden of approximately 851,150 hours (as monetized, is equivalent to an annual burden of $243.65 million)[157] plus outside costs of $38.4 million.[158] This translates to an annual burden per adviser of 71.2 hours (as monetized, is equivalent to an annual burden of $20,379) and $3,212.[159]

2. Rule 204–2

The currently-approved total annual burden estimate for rule 204–2 is 1,986,152 hours. This burden estimate was based on estimates that 10,946 advisers were subject to the rule, and each of these advisers spends an average of 181.45 hours preparing and preserving records in accordance with the rule. Based on updated data as of January 4, 2016, there are 11,956 registered investment advisers.[160] This increase in the number of registered investment advisers increases the total burden hours of current rule 204–2 from 1,986,152 to 2,169,417, an increase of 183,265 hours.[161]

The proposed amendments to rule 204–2 would require a registered investment adviser to maintain copies of the written business continuity and transition plans drafted under proposed rule 206(4)–4. In addition, the proposed amendments would require a registered investment adviser to retain copies of any records documenting the adviser's annual review of its policies and procedures under proposed rule 206(4)–4.

Based on staff experience, we estimate that the proposed amendments to rule 204–2 would increase each registered investment adviser's average annual collection burden under rule 204–2 by 2 hours, from 181.45 hours to 183.45 hours,[162] and would thus increase the annual aggregate burden for rule 204–2 by 23,912 hours,[163] from 2,169,417 hours to 2,193,328 hours.[164] As monetized, the estimated burden for each registered investment adviser's average annual burden under rule 204–2 would increase by approximately $150,[165] which would increase the estimated monetized aggregate annual burden for rule 204–2 by $1,793,325, from $162,706,275 to $164,499,600.[166] We estimate that there are no external costs associated with this collection of information under the proposed amendments to rule 204–2.

B. Request for Comment

We request comment on whether our estimates for burden hours and any external costs as described above are reasonable. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments in order to: (1) Evaluate whether the proposed collections of information are necessary for the proper performance of the function of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collections of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (4) determine whether there are ways to minimize the burden of the collections of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

The agency has submitted the proposed collection of information to OMB for approval. Persons wishing to submit comments on the collection of information requirements of the proposed amendments should direct them to the Office of Management and Budget, Attention Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and should send a copy to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090, with reference to File No. S7–13–16. OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication of this release; therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days after publication of this release. Requests for materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–13–16, and be submitted to the Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

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[149] This estimate is based on the following calculation: 10 hours × $400 = $4,000.

[150] This estimate is based on the following calculation: 30 hours × $400 = $12,000.

[151] This estimate is based on the following calculation: 50 hours × $400 = $20,000.

[152] This estimate is based on the following calculation: ($4,000 per smaller adviser × 2,032 smaller advisers) + ($12,000 per mid-sized adviser × 6,636 mid-sized advisers) + ($20,000 per larger adviser × 3,288 larger advisers) = $153.5 million.

[153] This estimate is based on the following calculations: $153.5 million/3 years = $51.2 million per year. $51.2 million/11,956 advisers = $4,282 per adviser.

[154] This estimate is based on the following calculations: 0.25 × 50 hours = 12.5 hours. 0.25 × $12,515 = $3,129. 0.25 × $4,000 = $1,000.

[155] This estimate is based on the following calculations: 0.25 × 250 hours = 62.5 hours. 0.25 × $70,045 = $17,511. 0.25 × $12,000 = $3,000.

[156] This estimate is based on the following calculations: 0.25 × 500 hours = 125 hours. 0.25 × $147,310 = $36,828. 0.25 × $20,000 = $5,000.

[157] This estimate is based on the following calculations: (2,032 smaller advisers × 12.5 hours) + (6,636 mid-sized advisers × 62.5 hours) + (3,288 larger advisers × 125 hours) = 851,150 hours. (2,032 smaller advisers × $3,129) + (6,636 mid-sized advisers × $17,511) + (3,288 larger advisers × $36,828) = $243.65 million.

[158] This estimate is based on the following calculation: (2,032 smaller advisers × $1,000) + (6,636 mid-sized advisers × $3,000) + (3,288 larger advisers × $5,000) = $38.4 million.

[159] This estimate is based on the following calculations: 851,150 hours/11,956 advisers = 71.2 hours per adviser. $243.65 million/11,956 advisers = $20,379 per adviser. $38.4 million/11,956 advisers = $3,212 per adviser.

[160] *See supra* note 140 and accompanying text.

[161] This estimate is based on the following calculations: (11,956 advisers − 10,946 advisers) * 181.45 hours = 183,265 hours; 183,265 hours + 1,986,152 hours = 2,169,417 hours.

[162] This estimate is based on the following calculation: 181.45 existing hours + 2 new hours = 183.45 hours.

[163] This estimate is based on the following calculation: 11,956 advisers × 2 hours = 23,912 hours.

[164] This estimate is based on the following calculation: 11,956 advisers × 183.45 hours = 2,193,328 hours.

[165] This estimate is based on the following calculation: 2 hours × $75 (hourly rate for an administrative assistant) = $150. The hourly wage used is from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified to account for an 1800-hour work-year and inflation (as of January 2016) and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[166] This estimate is based on the following calculations: 2,169,417 hours × $75 = $162,706,275. 2,193,328 hours × $75 = $164,499,600. $164,499,600 − $162,706,275 = $1,793,325.

IV. Initial Regulatory Flexibility Analysis

The Commission has prepared the following Initial Regulatory Flexibility Analysis ("IRFA") in accordance with section 3(a) of the Regulatory Flexibility Act[167] regarding our proposed rule 206(4)–4 and proposed amendments to rule 204–2.

A. Reasons for and Objectives of the Proposed Actions

Based on staff observations, we are concerned about the adequacy of some advisers' plans to address operational and other risks associated with business resiliency. Establishing strong operational controls that manage these risks, including the risks associated with business continuity and transition, are important practices and should increase the likelihood that advisers are as prepared as possible to continue operations on an ongoing basis and to meet client expectations and legal obligations in the event of a significant disruption in their operations. Accordingly, proposed rule 206(4)–4 would require SEC-registered advisers to adopt and implement written business continuity and transition plans reasonably designed to address operational and other risks related to a significant disruption in the investment adviser's operations.

We also are proposing specific components be included in such plans in order to address certain disparate practices the staff has previously observed during examinations and to facilitate robust business continuity and transition planning across all SEC-registered advisers. In addition, the proposed rule would require advisers to review their business continuity and transition plans at least annually in order to ensure that advisers are examining the continued adequacy and effectiveness of their plans on an ongoing basis.

The proposed amendments to rule 204–2 would require advisers to make and keep all business continuity and transition plans that are in effect or were in effect at any time within the past five years. The proposed amendments would help advisers have easy access to necessary information during periods of stress.

B. Legal Basis

Proposed rule 206(4)–4 is designed to address certain disparate practices our staff has previously observed during its examinations and to facilitate robust business continuity and transition planning across all SEC-registered advisers.

The Commission is proposing new rule 206(4)–4 and amendments to rule 204–2 under the rulemaking authority set forth in sections 204, 206(4) and 211(a) of the Advisers Act [15 U.S.C. 80b–4(b), 80b-6(4), and 80b-11(a)].

C. Small Entities Subject to the Rule and Rule Amendments

In developing these proposals, we have considered their potential impact on small entities that would be subject to proposed new rule 206(4)–4 and the proposed amendments to rule 204–2. The proposed new rule and the proposed amendments would affect all advisers registered with the Commission, including certain small entities. Under Commission rules, for the purposes of the Advisers Act and the Regulatory Flexibility Act, an investment adviser generally is a small entity if it: (1) Has assets under management having a total value of less than $25 million; (2) did not have total assets of $5 million or more on the last day of the most recent fiscal year; and (3) does not control, is not controlled by, and is not under common control with another investment adviser that has assets under management of $25 million or more, or any person (other than a natural person) that had total assets of $5 million or more on the last day of its most recent fiscal year.[168]

The proposed new rule and the proposed amendments would not apply to most advisers that are small entities ("small advisers") because small advisers are generally registered with one or more state securities authorities instead of with the Commission.[169] Based on IARD data, however, we estimate that as of January 4, 2016, approximately 515 small advisers are registered with the Commission.[170] Because these small advisers are registered, they, like all SEC-registered investment advisers, would all be subject to proposed new rule 206(4)–4 and the proposed amendments to rule 204–2.

D. Projected Reporting, Recordkeeping and Other Compliance Requirements

Proposed new rule 206(4)–4 and the proposed amendments to rule 204–2 would impose certain recordkeeping and other compliance requirements on all Commission-registered advisers, including Commission-registered small advisers. Proposed rule 206(4)–4 would require advisers to adopt and implement written business continuity and transition plans reasonably designed to address operational and other risks related to a significant disruption in the investment adviser's operations. The proposed amendments to rule 204–2 would require advisers to make and keep all business continuity and transition plans that are in effect or were in effect at any time within the past five years.

1. Rule 206(4)–4

As discussed in section II, we estimated that each adviser would incur one-time costs to adopt and implement a written business continuity and transition plan, as well as ongoing plan-related costs. As noted above, there are currently approximately 515 small advisers registered with the Commission. We estimate that each small adviser would incur an average initial burden of 50 hours associated with adopting and implementing a written business continuity and transition plan at a cost of $12,515.[171] Aggregating the estimated burden for all small advisers yields a total initial hourly burden of 25,750[172] (as monetized, is equivalent to a one-time aggregate burden of approximately $6,445,225).[173] Amortized over a three-year period, this would be an annual hourly burden of 16.7 per small adviser[174] (as monetized, is equivalent to an annual amortized burden per small adviser of $4,172).[175]

Our staff also anticipates that some small advisers may consult with outside legal counsel and/or other outside professionals to assist in drafting policies and procedures and/or to provide assistance in evaluating particular components of a plan. We estimate that the costs associated with such an engagement would include fees for approximately 10 hours for small firms at a rate of $400 per hour.[176] Consequently, for a representative smaller firm we estimate a total of $4,000 in outside fees.[177] Amortized over a three-year period, this would be an annual burden per small adviser of $1,333.[178] Accordingly, we estimate that the total annual initial burden on 515 small advisers for adopting and implementing a written business continuity and transition plan would be $686,495.[179]

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[167] 5 U.S.C. 603(a).

[168] Rule 0–7(a) under the Advisers Act.

[169] *See* section 203A of the Advisers Act, prohibiting most small advisers from registering with the Commission.

[170] Based on SEC-registered investment adviser responses to Form ADV, Item 5.F and Item 12.

[171] *See supra* note 141 (discussing the estimated initial cost burden associated with a representative smaller adviser).

[172] This estimate is based on the following calculation: 515 small advisers × 50 hours = 25,750 hours.

[173] This estimate is based on the following calculation: 515 small advisers × $12,515 = $6,445,225.

[174] This estimate is based on the following calculation: 50 hours/3 years = 16.7 hours per year.

[175] This estimate is based on the following calculations: $12,515/3 years = $4,172 per year.

In addition to the initial burden, a small adviser would incur ongoing, annual costs associated with its business continuity and transition plan, including the adviser annually reviewing the adequacy of its business continuity plan and the effectiveness of its implementation. Based on staff experience, we estimate that these ongoing costs would total approximately 25% of a small adviser's initial costs. Accordingly, we estimate that each small adviser would spend 12.5 hours annually on this effort internally while incurring outside costs of $1,000.[180] Aggregating the estimates above for 515 small advisers yields a total ongoing annual burden on small advisers of approximately 6,438 hours [181] plus outside costs of $515,000.[182]

2. Rule 204–2

The currently-approved annual aggregate information collection burden under rule 204–2 is 1,986,152 hours. This approved annual aggregate burden was based on estimates that 10,946 advisers were subject to the rule, of which 478 were small advisers, and each of these advisers spends an average of 181.45 hours preparing and preserving records in accordance with the rule. Based upon updated data as of January 4, 2016, there are 11,956 registered investment advisers,[183] of which 515 are small advisers.[184] The increase in the number of registered small advisers increases the total burden hours of current rule 204–2 on small advisers from 86,733 hours to 93,447 hours, an increase of 6,714 hours.[185]

The proposed amendments to rule 204–2 would require a registered investment adviser to maintain copies of the written business continuity and transition plans drafted under proposed rule 206(4)–4. In addition, the proposed amendments would require a registered investment adviser to retain copies of any records documenting the adviser's annual review of its policies and procedures under proposed rule 206(4)–4.

Based on staff experience, we estimate that the proposed amendments to rule 204–2 would increase each registered investment adviser's average annual collection burden under rule 204–2 by 2 hours, from 181.45 hours to 183.45 hours,[186] and would thus increase the annual aggregate burden for rule 204–2 by 1,030 hours,[187] from 93,447 hours to 94,477 hours.[188] As monetized, the estimated burden for each registered investment adviser's average annual burden under rule 204–2 would increase by approximately $150,[189] which would increase the estimated monetized aggregate annual burden for rule 204–2 by $77,250, from $7,008,525 to $7,085,775.[190] We estimate that there are no external costs associated with this collection of information under the proposed amendments to rule 204–2.

E. Duplicative, Overlapping, or Conflicting Federal Rules

We believe there are no federal rules that duplicate, overlap, or conflict with proposed new rule 206(4)–4 and the proposed amendments to rule 204–2. The written business continuity and transition plans that would be required by the proposed new rule would include certain policies and procedures already generally required by other rules under the federal securities laws, but the proposed new rule would not require these policies and procedures to be duplicated. Some of the records an adviser would be required to maintain under the proposed amendments to rule 204–2 also may be required records under the general recordkeeping provisions of rule 204–2 of the Advisers Act, but such overlap would be limited and the Commission would not require the adviser to maintain duplicate copies.

F. Significant Alternatives

In formulating our proposal, we have considered various reasonable alternatives to the individual elements of proposed new rule 206(4)–4 and the proposed amendments to rule 204–2, specifically as they relate to accomplishing our stated objectives while minimizing any significant economic impact on small entities. The alternatives most relevant to small advisers are discussed below. We have also requested comment relating to certain specific aspects of these and other alternatives above.[191]

The Commission considered exempting small advisers from the proposal entirely. The Commission also considered setting forth different business continuity and transition plan requirements for small advisers. However, because small advisers generally face the same types of transition and business continuity issues as larger advisers, although on a smaller scale, we believe small advisers should be subject to the proposed rule to the same extent as larger advisers and be allowed to tailor their business continuity and transition plans to the scope of their business. The proposed rule allows each adviser the necessary flexibility in creating a business continuity and transition plan to take into account the adviser's own unique operations, the nature and complexity of its business, its clients, and its key personnel, and we believe that such flexibility may result in small advisers incurring less costs to comply.[192]

G. Solicitation of Comments

We encourage written comments on matters discussed in this IRFA. We solicit comment on the number of small entities subject to the proposed rule and whether the proposed rule discussed in this release could have an effect on small entities that has not been considered. We request that commenters describe the nature of any impact on small entities and provide empirical data to support the extent of such impact.

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[176] *See supra* note 148 and accompanying text.

[177] This estimate is based on the following calculation: 10 hours × $400 per hour = $4,000.

[178] This estimate is based on the following calculation: $4,000/3 years = $1,333 per year.

[179] This estimate is based on the following calculations: 515 small advisers × $1,333 = $686,495.

[180] This estimate is based on the following calculations: 0.25 × 50 hours = 12.5 hours. 0.25 × $4,000 = $1,000.

[181] This estimate is based on the following calculation: 12.5 hours × 515 advisers = 6,438 hours.

[182] This estimate is based on the following calculation: $1,000 × 515 advisers—$515,000.

[183] *See supra* note 140 and accompanying text.

[184] *See supra* note 170 and accompanying text.

[185] This estimate is based on the following calculations: 515 small advisers × 181.45 hours = 93,447 hours. 478 small advisers × 181.45 hours = 86,733 hours. 93,447 − 86,733 = 6,714.

[186] This estimate is based on the following calculation: 181.45 existing hours + 2 new hours = 183.45 hours.

[187] This estimate is based on the following calculation: 515 small advisers × 2 hours = 1,030 hours.

[188] This estimate is based on the following calculation: 515 small advisers × 183.45 hours = 94,477 hours.

[189] This estimate is based on the following calculation: 2 hours × $75 (hourly rate for an administrative assistant) = $150. The hourly wage used is from SIFMA's Management & Professional Earnings in the Securities Industry 2013, modified to account for an 1800-hour work-year and inflation (as of January 2016) and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[190] This estimate is based on the following calculations: 93,447 hours × $75 = $7,008,525. 94,477 hours × $75 = $7,085,775. $7,085,775 − $7,008,525 = $77,250.

[191] *See supra* section I.C.1.f.

[192] *See supra* section III.A.1, discussing the lower estimated cost burdens, both initial and ongoing, associated with smaller advisers as compared to larger advisers.

V. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, or "SBREFA," [193] we must advise OMB whether a proposed regulation constitutes a "major" rule. Under SBREFA, a rule is considered "major" where, if adopted, it results in or is likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effects on competition, investment or innovation.

We request comment on the potential impact of the proposed rule on the economy on an annual basis. Commenters are requested to provide empirical data and other factual support for their views to the extent possible.

VI. Statutory Authority

The Commission is proposing new rule 206(4)–4 and amendments to rule 204–2 under the rulemaking authority set forth in sections 204, 206(4) and 211(a) of the Advisers Act [15 U.S.C. 80b–4, 80b–6(4), and 80b–11(a)].

List of Subjects in 17 CFR Part 275

Investment advisers, Reporting and recordkeeping requirements.

Text of Proposed Rule Amendments

For reasons set out in the preamble, title 17, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 1. The authority citation for part 275 continues to read, in part, as follows:

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(11)(H), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, and 80b–11, unless otherwise noted.

* * * * *

Section 275.204–2 is also issued under 15 U.S.C. 80b–6.

* * * * *

■ 2. Section 275.204–2 is amended by:
■ a. Reserving paragraph (a)(19);
■ b. Adding paragraph (a)(20); and
■ c. Revising paragraph (e)(1).

The addition and revision read as follows:

§ 275.204–2 Books and records to be maintained by investment advisers.

(a) * * *

(20)(i) A copy of the investment adviser's business continuity and transition plan formulated pursuant to § 275.206(4)–4 that is in effect, or at any time within the past five years was in effect;

(ii) Any records documenting the investment adviser's annual review of the business continuity and transition plan conducted pursuant to § 275.206(4)–4(b).

* * * * *

(e)(1) All books and records required to be made under the provisions of paragraphs (a) through (c)(1)(i), and (c)(2) of this section (except for books and records required to be made under the provisions of paragraphs (a)(11), (a)(12)(i), (a)(12)(iii), (a)(13)(ii), (a)(13)(iii), (a)(16), (a)(17)(i), and (a)(20)(i) of this section), shall be maintained and preserved in an easily accessible place for a period of not less than five years, from the end of the fiscal year during which the last entry was made on such record, the first two years in an appropriate office of the investment adviser.

* * * * *

■ 3. Section 275.206(4)–4 is added to read as follows:

§ 275.206(4)–4 Investment adviser business continuity and transition plan.

(a) *Prohibition.* If you are an investment adviser registered or required to be registered under section 203 of the Act (15 U.S.C. 80b–3), it shall be unlawful within the meaning of section 206 of the Act (15. U.S.C. 80b–6) for you to provide investment advice to your clients unless you:

(1) *Business continuity and transition plan.* Adopt and implement a written business continuity and transition plan; and

(2) *Annual review.* Review, no less frequently than annually, the adequacy of the business continuity and transition plan and the effectiveness of its implementation.

(b) *Content of business continuity and transition plan.* (1) For purposes of this section, the term *business continuity and transition plan* means policies and procedures reasonably designed to address operational and other risks related to a significant disruption in the investment adviser's operations, including policies and procedures concerning:

(i) Business continuity after a significant business disruption; and

(ii) Business transition in the event the investment adviser is unable to continue providing investment advisory services to clients.

(2) The content of a business continuity and transition plan shall be based upon risks associated with the adviser's operations and shall include policies and procedures designed to minimize material service disruptions, including policies and procedures that address the following:

(i) Maintenance of critical operations and systems, and the protection, backup, and recovery of data, including client records;

(ii) Pre-arranged alternate physical location(s) of the adviser's office(s) and/or employees;

(iii) Communications with clients, employees, service providers, and regulators;

(iv) Identification and assessment of third-party services critical to the operation of the adviser; and

(v) Plan of transition that accounts for the possible winding down of the investment adviser's business or the transition of the investment adviser's business to others in the event the investment adviser is unable to continue providing investment advisory services, that includes the following:

(A) Policies and procedures intended to safeguard, transfer, and/or distribute client assets during transition;

(B) Policies and procedures facilitating the prompt generation of any client-specific information necessary to transition each client account;

(C) Information regarding the corporate governance structure of the adviser;

(D) Identification of any material financial resources available to the adviser; and

(E) An assessment of the applicable law and contractual obligations governing the adviser and its clients, including pooled investment vehicles, implicated by the adviser's transition.

By the Commission.

Dated: June 28, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–15675 Filed 7–1–16; 8:45 am]

BILLING CODE 8011–01–P

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[193] Public Law 104–121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C. and as a note to 5 U.S.C. 601).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 375 and 388

[Docket No. RM16–15–000]

Regulations Implementing FAST Act Section 61003—Critical Electric Infrastructure Security and Amending Critical Energy Infrastructure Information

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) proposes to amend the Commission's regulations to implement provisions of the Fixing America's Surface Transportation Act that pertain to the designation, protection and sharing of Critical Electric Infrastructure Information. Separately, the Commission proposes to amend its regulations that pertain to Critical Energy Infrastructure Information.

DATES: Comments are due August 19, 2016.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways:

- Electronic Filing through *http://www.ferc.gov.* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.
- *Mail/Hand Delivery:* Those unable to file electronically may mail or hand-deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures Section of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Introduction

1. On December 4, 2015, the President signed into law the Fixing America's Surface Transportation (FAST) Act.[1] The FAST Act, *inter alia,* added section 215A to the Federal Power Act (FPA) to improve the security and resilience of energy infrastructure in the face of emergencies.[2] The FAST Act directs the Commission to issue regulations aimed at securing and sharing sensitive infrastructure information. Specifically, FPA section 215A(d)(2) (Designation and Sharing of Critical Electric Infrastructure Information) requires the Commission to "promulgate such regulations as necessary to":

(A) establish criteria and procedures to designate information as critical electric infrastructure information;

(B) prohibit the unauthorized disclosure of critical electric infrastructure information;

(C) ensure there are appropriate sanctions in place for Commissioners, officers, employees, or agents of the Commission or the Department of Energy [DOE] who knowingly and willfully disclose critical electric infrastructure information in a manner that is not authorized under this section; and

(D) taking into account standards of the Electric Reliability Organization, facilitate voluntary sharing of critical electric infrastructure information with, between, and by—(i) Federal, State, political subdivision, and tribal authorities; (ii) the Electric Reliability Organization; (iii) regional entities; (iv) information sharing and analysis centers established pursuant to Presidential Decision Directive 63; (v) owners, operators, and users of critical electric infrastructure in the United States; and (vi) other entities determined appropriate by the Commission.

2. The Commission proposes to revise 18 CFR 375.313, 388.112, and 388.113 of the Commission's regulations to implement the requirements identified in section 215A(d)(2) of the FPA, as well as other provisions included in the FAST Act. The Commission also proposes modifications to its existing Critical Energy Infrastructure Information process, in part, to comply with the FAST Act. The amended process will be referred to as the Critical Energy/Electric Infrastructure Information (CEII) process. Thus, these changes are intended to comply with the FAST Act as well as improve the overall efficiency of the CEII process for information that is submitted to or is generated by the Commission.

II. Background

3. Shortly after the terrorist attacks on September 11, 2001, the Commission took steps to protect information that it considered Critical Energy Infrastructure Information.[3] As a preliminary step, the Commission removed from its public files and eLibrary document retrieval system documents that were likely to contain detailed specifications of facilities, and directed the public to use the Freedom of Information Act (FOIA) request process to obtain such information.[4] In 2003, the Commission established its Critical Energy Infrastructure Information procedures for entities outside of the Commission to obtain access to Critical Energy Infrastructure Information, stating that such information would typically be exempt from disclosure pursuant to FOIA.[5] In particular, the Commission determined that it was important to have a process for individuals with a valid or legitimate need to access certain sensitive energy infrastructure information.

4. The Commission last revised its Critical Energy Infrastructure Information rules over eight years ago.[6] However, the Commission indicated that it will revise the Critical Energy Infrastructure Information rules based on a continuing review of its application and effectiveness.[7]

5. Over 7,000 documents are submitted to the Commission's eLibrary

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[1] *See* Fixing America's Surface Transportation, Public Law 114–94, 129 Stat. 1312 (2015) (to be codified at 16 U.S.C. 824 *et seq.*) (FAST Act).

[2] *Id.* 61,003.

[3] *See Statement of Policy on Treatment of Previously Public Documents,* 66 FR 52,917 (Oct. 18, 2001), 97 FERC ¶ 61,030 (2001). A large component of what is currently Critical Energy Infrastructure Information was previously publicly available prior to September 11, 2001.

[4] The FOIA process is specified in 5 U.S.C. 552 and the Commission's regulations at 18 CFR 388.108.

[5] *Critical Energy Infrastructure Information,* Order No. 630, 68 FR 9,857 (Mar. 3, 2003), FERC Stats. & Regs. ¶ 31,140 (2003), *order on reh'g,* Order No. 630–A, 68 FR 46,456 (Aug. 6, 2003), FERC Stats. & Regs. ¶ 31,147 (2003).

[6] *See Critical Energy Infrastructure Information,* Order No. 702, 72 FR 63,980 (Nov. 14, 2007), FERC Stats. & Regs. ¶ 31,258 (2007).

[7] For example, in 2014, the Department of Energy Inspector General initiated a review of the Commission's controls for protecting non-public information. In a report dated January 30, 2015, the DOE Inspector General recommended, among other things, that the Commission take steps to ensure that the Critical Energy Infrastructure Information processes to protect and control non-public information are current and that such policies are disseminated and properly implemented. DOE Inspector General, *Inspection Report: Review of Controls for Protecting Nonpublic Information at the Federal Energy Regulatory Commission* (Jan. 2015), *http://energy.gov/sites/prod/files/2015/02/f19/DOE-IG-0933.pdf* (DOE IG Report).

system as Critical Energy Infrastructure Information each year. The vast majority of submissions and Commission-generated information relates to hydroelectric projects but also includes information regarding natural gas pipeline and electric infrastructure.

6. The Commission receives approximately 200 requests for Critical Energy Infrastructure Information a year. Requests are typically submitted by public utilities, gas pipelines, Liquefied Natural Gas (LNG) facilities, hydroelectric developers, academics, landowners, public interest groups, researchers, renewable energy organizations, consultants, and Federal agencies.

7. The Commission's current Critical Energy Infrastructure Information rules provide a means for entities to obtain Critical Energy Infrastructure Information while ensuring that it is handled in an appropriate and secure manner. The new requirements in section 215A(d) also ensure that Critical Electric Infrastructure Information, which as described below includes Critical Energy Infrastructure Information, can be appropriately shared while also being adequately protected. Thus, the Commission proposes to augment its existing Critical Energy Infrastructure Information process to comply with section 215A(d)(2) and to make other changes described in this NOPR. The Commission proposes to have a single process that would address submitting, designating, handling, sharing, and disseminating CEII that is submitted to or generated by the Commission. The proposed regulations will govern how the Commission and its employees implement the provisions of the FAST Act.

III. Revisions To Implement the FAST Act

A. Relocating References to CEII From Section 388.112 to Section 388.113

8. The Commission proposes to transfer provisions contained in section 388.112 that are applicable to Critical Energy Infrastructure Information to amended section 388.113. This transfer would include notice and filing requirements. As a result of this change, amended section 388.112 would apply only to information designated as privileged and all of the Commission's CEII procedures will be in section 388.113.

B. Scope, Purpose, and Definitions

9. The Commission's current Critical Energy Infrastructure Information process is designed to limit the distribution of sensitive infrastructure information to those individuals with a need to know in order to avoid having sensitive information fall into the hands of those who may use it to attack the nation's infrastructure. Section 388.113(c) of the Commission's regulations defines Critical Energy Infrastructure Information as:

> specific engineering, vulnerability, or detailed design information about proposed or existing critical infrastructure that:
> (i) Relates details about the production, generation, transportation, transmission, or distribution of energy;
> (ii) Could be useful to a person in planning an attack on critical infrastructure;
> (iii) Is exempt from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552; and
> (iv) Does not simply give the general location of the critical infrastructure.

10. To augment the current Critical Energy Infrastructure Information process to comply with FPA section 215A(d), the Commission proposes that the scope and purpose of its regulations be changed to reflect the requirements of the FAST Act. Specifically, the Commission proposes to amend section 388.113(a) to indicate that the section governs the procedures for submitting, designating, handling, sharing, and disseminating CEII submitted to or generated by the Commission. Moreover, the Commission proposes to amend section 388.113(b) to indicate that the purpose of section 388.113 is to provide an overview of the Commission's CEII procedures.

11. Section 215A(a)(3) of the FPA introduces the new term "Critical Electric Infrastructure Information:"

> information related to critical electric infrastructure, or proposed critical electrical infrastructure, generated by or provided to the Commission or other Federal agency, other than classified national security information . . . Such term includes information that qualifies as critical energy infrastructure information under the Commission's regulations.

As indicated above, the Commission's current procedures for Critical Energy Infrastructure Information apply to information "about the production, generation, transportation, transmission, or distribution of energy." Thus, the FAST Act defines "Critical Electric Infrastructure Information" to include not only information regarding the Bulk-Power System but also information regarding other energy infrastructure (*i.e.*, gas pipelines, LNG, oil, and hydroelectric infrastructure) to the extent such information qualifies as Critical Energy Infrastructure Information under the Commission's current regulations.

12. Accordingly, the Commission proposes to revise section 388.113(c) (Definitions) of the Commission's regulations to add the new statutory term Critical Electric Infrastructure Information, as referenced above. The Commission also proposes to add to the regulations the term Critical Electric Infrastructure, which is defined in FPA section 215A(a)(3) as "a system or asset of the bulk-power system, whether physical or virtual, the incapacity or destruction of which would negatively affect national security, economic security, public health or safety, or any combination of such matters."

13. The Commission proposes to refer to the information under the new regulations as Critical Energy/Electric Infrastructure Information, and to use the abbreviation "CEII" for this term.[8] By referring to the information only as Critical Electric Infrastructure Information, the public, especially those that do not interact with the Commission on a regular basis, may assume that the revised CEII regulations only cover information regarding electric infrastructure and not also information about other energy infrastructure. By using the term Critical Energy/Electric Infrastructure Information, the Commission clearly conveys to the public that the Commission's revised CEII procedures cover more than just electric infrastructure.

14. The Commission complies with section 215A(d) by incorporating the term Critical Electric Infrastructure Information into its regulations as set forth in the statute and treating it as Congress intended. In addition, subsuming Critical Energy Infrastructure Information into the term Critical Electric Infrastructure Information will allow the Commission to have a unitary process for handling CEII and, thereby, avoid any confusion that could result from multiple processes for different types of critical infrastructure information. Avoiding such confusion should better facilitate sharing of CEII as well as help prevent unauthorized disclosures of CEII, which we see as the principal goals of section 215A(d).

15. Section 215A(d)(1)(A) of the FPA states that Critical Electric Infrastructure Information "shall be exempt from disclosure under [(FOIA)] section 552(b)(3)."[9] Accordingly, the Commission proposes to amend its regulations to specify that CEII is

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[8] The abbreviation will be used except where appropriate to address any distinction between the Commission's current regulations and the terms of the FAST Act.

[9] *See* 5 U.S.C. 552(b)(3) (protects information "specifically exempted from disclosure by statute").

exempt from disclosure under FOIA pursuant to section 215A(d)(1)(A).[10]

C. Criteria and Procedures for Determining What Constitutes CEII

16. Section 215A(d)(2)(A) requires the Commission to "establish criteria and procedures to designate information as critical electric infrastructure information." [11] The proposed processes and procedures are intended to apply to the manner in which the Commission handles CEII that is submitted to or generated by the Commission.[12]

17. Accordingly, the Commission proposes to amend section 388.113(d) of its regulations to provide that information submitted to or generated by the Commission is CEII if it meets the definition, and the criteria provided below.[13] The Commission therefore proposes to merge its existing criteria with the statutory directives in the FAST Act. The Commission further proposes to amend its procedures, as explained below.

1. Designation of Submissions to the Commission

18. Existing section 388.112(b) requires that a submitter of Critical Energy Infrastructure Information clearly mark the information as CEII and provide a justification for the designation. The Commission will maintain these requirements in section 388.113(d) for CEII. However, in addition to this information, the Commission proposes to include in section 388.113(d) a requirement that each submitter include on the information submitted a clear statement of the date the information was submitted to the Commission, and how long the submitter believes the CEII designation should apply to the information.[14] The referenced justification that the submitter submits must include an explanation for the period proposed. Such information will assist the Commission in making a determination as to the length of time the information should be designated as CEII. Failure to follow these submission requirements, including failure to provide an adequate justification, could result in denial of the designation and public release of the information.

19. Under its current practice, the Commission deems the designation on a submission accepted as submitted, unless the submitter is otherwise notified by the Commission.[15] The Commission intends to follow that same practice under the new CEII regulations. However, the Commission maintains the discretion to check a submission at the time of submission to ensure that it includes adequate designation information and is properly designated. In sum, the burden will be on the submitting entity to ensure that the information it submits is properly labeled and contains adequate designation information. Although unmarked information may be eligible for CEII treatment, the Commission intends to treat information as CEII only if it is properly designated as CEII pursuant to our regulations.

20. To ensure that all the requirements concerning CEII are in a single section of the Commission's regulations, the Commission proposes to move the requirements in current section 388.112(b) regarding CEII to section 388.113(d). The Commission believes that it will better protect CEII from unauthorized disclosure as well as facilitate the voluntary sharing of CEII to have a single process to address CEII and for that process to be located in a single section of our regulations. Locating our CEII regulations in the same section of the Commission's regulations will relieve the public from having to review multiple sections of our regulations to find our rules addressing CEII, which may cause confusion.

2. Designation of Commission-Generated Information

21. The Commission proposes to revise section 388.113(d) to specify that, for Commission-generated information, the Office Director for the Commission office in which the Commission-generated information was created, or the Office Director's designee, must consult with the Coordinator to determine whether the information meets the definition of CEII, how long the designation of CEII should last and, as appropriate, any re-designation. The Coordinator will then make the designation determination.[16] Any CEII that the Commission generates must also be clearly marked as CEII and indicate the date that the information was designated as CEII. This coordination will help ensure that Commission-generated information is handled in an appropriate and consistent manner.

3. Segregable Information

22. In many cases, information submitted to the Commission may contain information that is CEII along with information that is not CEII. Section 215A(d)(8) requires the Commission to:

> segregate critical electric infrastructure information or information that reasonably could be expected to lead to the disclosure of the critical electric infrastructure information within documents and electronic communications, wherever feasible, to facilitate disclosure of information that is not designated as critical electric infrastructure information.

Accordingly, the Commission proposes to add a provision to section 388.113(d) that would require the submitter to segregate CEII (or information that reasonably could be expected to lead to the disclosure of the CEII) from non-CEII at the time of submission wherever feasible. The burden would be on the submitter to clearly mark in the submission what is CEII and what is not CEII. The requirement also would apply to Commission-generated CEII.[17]

4. Duration of Designation

23. Section 215A(d)(9) of the FPA states that information "may not be

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[10] The Commission has relied upon FOIA Exemption 7(F) to protect this type of information from disclosure. *See* 5 U.S.C. 552(b)(7)(F) (protecting law enforcement information that could reasonably be expected to endanger the life or physical safety of any individual). The Commission will continue to rely on this exemption, as appropriate.

[11] Section 215A(d)(3) gives the Commission and DOE the authority to designate Critical Electric Infrastructure Information.

[12] Section 215A(d)(3) provides that information "may be designated" by the Commission or Secretary of Energy as "critical electric infrastructure information." These proposed regulations would only apply to information submitted to or generated by the Commission. Nothing in the preamble or proposed regulations would limit DOE's ability to designate information as it deems appropriate under the FAST Act.

[13] Information downloaded by Commission staff from private databases that are accessed pursuant to Commission order or regulation will be maintained as non-public information consistent with the Commission's internal controls. *See, e.g., Availability of Certain North American Electric Reliability Corporation Databases to the Commission,* 155 FERC ¶ 61,275 (2016). If the Commission receives a request for access to downloaded information, the Commission will evaluate whether the information meets the definition of CEII or is proprietary information or otherwise privileged or non-public and will provide the owner of the database or information (as appropriate) with an opportunity to comment on the request consistent with proposed section 388.113(d)(1)(vi) or sections 388.112(d) and (e).

[14] The submitter must clearly indicate this information on the submission in a clear and durable manner. For example, in addition to an appropriate cover sheet, each page should be clearly labeled. The date of submission will start the period for CEII designation. Commission-generated information should also have clear markings.

[15] Section 18 CFR 375.313 delegates authority to the Critical Energy Infrastructure Information Coordinator (Coordinator), who is the Director of the Office of External Affairs. As explained below, the Commission proposes to modify this section to reflect the new authority in the FAST Act.

[16] Pursuant to section 375.313(d) of the Commission's regulations, the Coordinator is responsible for establishing "reasonable conditions" on the release of CEII.

[17] *See* proposed 18 CFR 388.113(d)(2) and (3).

designated as critical electric infrastructure information for longer than 5 years, unless specifically re-designated by the Commission or the Secretary, as appropriate." The Commission proposes to add this statement to proposed section 388.113(e).

24. The Commission plans to use the following process to implement the duration of designation provision. At the present time there are almost 200,000 documents labeled as Critical Energy Infrastructure Information in the Commission's eLibrary system. The Commission does not plan to move designated information from its non-public files to its public files after the designation period has passed (*i.e.*, up to five years from date of designation), unless the Commission determines in a particular instance that it is appropriate to do so. The passing of the CEII designation period would not necessarily render designated information suitable for inclusion in the Commission's public files. The Commission plans to determine whether information should be re-designated or alternatively placed in the Commission's public files when an entity requests the information, when staff determines a need to remove the designation, or when a submitter requests that information no longer be treated as CEII.[18]

25. The proposed approach is consistent with the FAST Act. Section 215A(d)(9) of the FPA does not require automatic public disclosure of CEII at the end of the initial CEII designation period. Indeed, the FAST Act contemplates that there may be information that warrants continued protection after the initial designation period. Given the volume of CEII in the Commission's files and the expectation that the Commission will continue to receive a substantial amount of CEII each year, this proposed approach strikes a reasonable balance in meeting the designation requirements of the FAST Act.

26. Consistent with the above practice, the Commission proposes that the non-disclosure agreement (NDA) will require any recipient of CEII from the Commission to continue to protect the information past the expiration of the CEII designation marked on the information. Further, the recipient must receive prior authorization from the Commission before making any disclosure of such information. These requirements will enable the Commission to comply with section 215A(d)(10) and determine whether information must be "specifically re-designated" as CEII.

27. Section 215A(d)(10) of the FPA provides that when "the Commission or the [DOE] Secretary, as appropriate, determines that the unauthorized disclosure of such information could no longer be used to impair the security or reliability of the bulk-power system or distribution facilities" the designation shall be removed. The Commission proposes to revise section 388.113(e) of the Commission's regulations to provide for removal of the CEII designation when it no longer could impair the security or reliability of not only the Bulk-Power System and distribution facilities but also other forms of energy infrastructure. The Commission will provide notice to the submitter in the instance where the Commission takes the affirmative step to rescind the designation.

5. Judicial Review of Designation

28. Section 215A(d)(11) of the FPA provides that:

> any determination by the Commission or the [DOE] Secretary concerning the designation of critical electric infrastructure information . . . shall be subject to review . . . in the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in the District of Columbia.

The Commission proposes to incorporate this provision into proposed section 388.113(e) of its regulations. In addition, the Commission proposes to require an entity or individual that intends to challenge a Commission designation determination in federal district court to first appeal the decision to the Commission's General Counsel. We believe that requiring an administrative appeal prior to seeking judicial review is appropriate because it would ensure consistency in how the Commission addresses CEII determinations, and is consistent with the current practice for responding to CEII and FOIA requests.[19]

D. Duty To Protect CEII

29. Whether CEII is created by Commission staff or submitted to the Commission by an outside party or a member of the public, section 215A(d)(2)(B) of the FPA requires the Commission to "prohibit the unauthorized disclosure of critical electric infrastructure information." This requirement applies to Commission employees as well as to all individuals to whom the Commission provides CEII. Thus, the Commission proposes to make the following changes to its regulations in proposed section 388.113(h) to ensure CEII is adequately protected.

1. Internal Controls for Commission Employees

30. To ensure that Commission employees appropriately handle CEII, Commission staff is developing an information governance policy and guidelines, which is intended to address how sensitive information, including CEII, should be handled, marked, and kept secure.[20] Consistent with these guidelines, the Commission proposes to add a provision in proposed section 388.113(h) that would require the Commissioners, Commission staff, and Commission contractors to comply with the Commission's internal controls. The internal controls will address how the Commission and its personnel, including contractors and agents, handle CEII.

2. Controls for Recipients of CEII

31. Currently, section 388.113(d) requires external recipients of Critical Energy Infrastructure Information to sign an NDA, which imposes conditions on how the information may be used.[21] The current regulation does not specify the minimum required content of an NDA.

32. The Commission proposes to strengthen the NDA requirements for all the different forms of NDAs the Commission uses to share CEII.[22] Including these provisions in each type of NDA form that the Commission uses will better protect CEII from unauthorized disclosure. Specifically, the Commission proposes revising its regulations to state in section 388.113(h)(2) that an NDA must minimally require that CEII: (1) Will only be used for the purpose it was requested; (2) may only be discussed with authorized recipients; (3) must be kept in a secure place in a manner that would prevent unauthorized access; (4)

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[18] In the event the Commission re-designates information as CEII, the Commission will re-designate the information as CEII for another five years or a shorter time period, as appropriate.

[19] Such a determination is subject to review by an applicable district court and would not be an order subject to rehearing and review under 16 U.S.C. 825l.

[20] The DOE IG Report raised concerns with how Commission staff handled, labeled, and tracked Critical Energy Infrastructure Information. DOE IG Report at 2–5, 12.

[21] *See, e.g.*, General Non-Disclosure Agreement, *http://www.ferc.gov/legal/ceii-foia/ceii/gen-nda.pdf.*

[22] Separate NDAs exist for general users, the media, state agencies, and consultants, and are available at *http://www.ferc.gov/legal/ceii-foia/ceii.asp.* Federal Agency requesters, as noted below, receive an Agency Acknowledgment and Agreement, which has different terms than the NDAs.

must be destroyed or returned to the Commission upon request; and (5) that the Commission may audit compliance with the NDA. These changes would codify and strengthen current NDA terms consistent with FPA section 215A(d).

33. Moreover, another means to prevent unauthorized disclosure of CEII is to ensure that the CEII is only shared with those who need it. The Commission, therefore, proposes to amend section 388.113(g)(5) to require a person seeking CEII to demonstrate a legitimate need for the information. Thus, the Commission proposes to require a requestor to demonstrate: (1) The extent to which a particular function is dependent upon access to the information; (2) why the function cannot be achieved or performed without access to the information; (3) whether other information is available to the requester that could facilitate the same objective; (4) how long the information will be needed; (5) whether or not the information is needed to participate in a specific proceeding (with that proceeding identified); and (6) whether the information is needed expeditiously. This information will assist the Commission's CEII Coordinator in "balance[ing] the requestor's need for the information against the sensitivity of the information." [23] A conclusory statement will not satisfy this requirement.

34. Finally, to ensure that CEII is only disclosed to appropriate individuals, the Commission proposes to amend section 388.113(g)(5)(i)(D) to require the requestor to include a signed statement attesting to the accuracy of the information provided in any request for CEII submitted to the Commission.

E. Sanctions

35. Section 215A(d)(2)(C) of the FPA requires the Commission to "ensure there are appropriate sanctions in place for Commissioners, officers, employees, or agents of the Commission or the Department of Energy who knowingly and willfully disclose critical electric infrastructure information in a manner that is not authorized under this section." The Commission proposes to add proposed section 388.113(i) to implement this requirement.

36. The Commission proposes that it take responsibility for addressing unauthorized disclosures of CEII in the Commission's possession by Commission personnel.[24] The Commission may initiate an adverse personnel action, such as a suspension or a removal action, against a Commission employee who makes an unauthorized disclosure of CEII or any other non-public information.[25] While the Commission may not sanction the Chairman or Commissioners,[26] it can refer any misconduct by the Chairman or Commissioners to the DOE Inspector General.

F. Voluntary Sharing of CEII

37. Section 215A(d)(2)(D) of the FPA requires that the Commission:

> taking into account standards of the Electric Reliability Organization, facilitate voluntary sharing of critical electric infrastructure information with, between, and by—(i) Federal, State, political subdivision, and tribal authorities; (ii) the Electric Reliability Organization; (iii) regional entities; (iv) information sharing and analysis centers established pursuant to Presidential Decision Directive 63; (v) owners, operators, and users of critical electric infrastructure in the United States; and (vi) other entities determined appropriate by the Commission.

Under this provision, the Commission has authority to share CEII with individuals and organizations that the Commission has determined need the information to ensure that energy infrastructure is protected.[27] Voluntary sharing applies to both Commission-generated CEII and CEII submitted to the Commission.

38. Under this provision, the Commission may share CEII without first receiving a request for the CEII. Section 388.112(c)(i) already provides the Commission with "the discretion to release information as necessary to carry out its jurisdictional responsibilities." The Commission proposes to move this language to section 388.113(f)(2) in the regulations and also note that the Commission retains the discretion to release information as necessary for other federal agencies to carry out their jurisdictional responsibilities.

39. The Commission also proposes to add section 388.113(f)(1) to its regulations to require an Office Director or his designee to consult with the Coordinator prior to the Office Director or his designee making a determination to voluntarily share CEII. The Coordinator will determine whether the information has been appropriately designated as CEII and whether appropriate protective measures are in place to secure its transfer and treatment by the recipient.

40. When the Commission voluntarily shares information, the CEII will be shared subject to an appropriate NDA or Acknowledgement and Agreement.[28] Thus, the Commission proposes to add language to its regulations in proposed section 388.113(f) to make clear that, after a determination by the Coordinator, the Office Director will provide the proposed recipients of the CEII with the appropriate NDA or Agency Acknowledgement and Agreement for execution and return. The Commission proposes to amend its regulations to require a signed copy of each agreement be maintained by the Office Director with a copy to the Coordinator.

41. The Commission proposes to add to section 388.113(f) of its regulations a statement indicating that the Commission may impose additional restrictions on how the CEII the Commission voluntarily shares may be used and maintained. Given that the Commission anticipates that it will voluntarily share CEII when the Commission believes that the recipients need the information to protect critical infrastructure, the recipients may otherwise have no other legitimate need for the information but to address that event. Thus, it is appropriate to impose additional conditions on use and handling of CEII that the Commission voluntarily shares.

42. Where practicable, when the Commission is considering voluntarily sharing CEII, the Commission will provide notice to the submitter of that information. However, it may not be practicable for the Commission to provide notice to the submitter in instances where voluntary sharing is necessary to maintain infrastructure security, to address a potential threat, or in other exigent circumstances. In such instances, a requirement to give notice to the submitter may be detrimental to the ability of the Commission to timely share CEII with entities that may urgently need the information and could compromise law enforcement

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[23] *See* 18 CFR 388.113(d)(4)(iii) and (iv).

[24] The Commission anticipates that DOE will take responsibility for sanctions for unauthorized disclosures by its officers, employees, staff, and agents with regard to information in DOE's possession.

[25] *See, e.g.*, 5 U.S.C. Chapter 75 (Adverse Actions).

[26] The Chairman and Commissioners are appointed by the President and may be removed by the President only for inefficiency, neglect of duty, or malfeasance in office. 42 U.S.C. 7171.

[27] Section 215A(d)(6) of the FPA makes clear that nothing in the FAST Act "require[s] a person or entity in possession of critical electric infrastructure information to share such information" with other individuals and entities; *see also* Cybersecurity Information Sharing Act of 2015, Public Law 114–113, 129 Stat. 2936 (2015).

[28] As noted below, to obtain CEII Federal Agencies execute an Acknowledgement and Agreement, as opposed to an NDA. *See* Federal Agency Acknowledgement and Agreement, *http://www.ferc.gov/legal/ceii-foia/ceii/fed-agen-acknow-agree.pdf.*

operations.[29] Thus, under these limited circumstances, the Commission will not give the submitter notice of sharing the CEII with others. However, to be clear, any CEII that the Commission voluntarily shares under these circumstances will be handled as CEII subject to an NDA or an Acknowledgement and Agreement and, as explained above, may be subject to additional controls as appropriate.

IV. Other Proposed Revisions

A. Request for Access to CEII

1. Owner-Operator Requests

43. Existing sections 388.113(d)(1) and (2) permit Critical Energy Infrastructure Information to be released directly to owner/operators outside of the Critical Energy Infrastructure Information process. The DOE IG Report raised concerns that the Commission might not be aware of information released outside of the Critical Energy Infrastructure Information process.[30] The Commission proposes to maintain this practice but proposes to amend existing sections 388.113(d)(1) and (2), re-designated as proposed sections 388.113(g)(1) and (2), to require Commission staff to inform the Coordinator of such requests prior to the release of any information.

44. Additionally, the Commission proposes to amend existing section 388.113(d)(1), which allows an owner or operator of a facility to obtain certain CEII concerning its facilities without signing an NDA, to exclude Commission-generated information except inspection reports/operation reports and any information directed to the owner-operators. Thus, the owners and operators of a facility will be able to obtain inspection reports/operation reports and any information directed to the owner-operators concerning their facilities without going through the CEII process.

45. In Order No. 630, the Commission relieved owners/operators from signing an NDA for Critical Energy Infrastructure Information regarding their own facilities on the basis that "they have at least as great an incentive to protect this information as the Commission has."[31] We believe that owners/operators will have the same incentive to protect inspection reports/operation reports and any information regarding their own facilities that may contain Commission-generated CEII.

2. Federal Agency Requests

46. Existing section 388.113(d)(2) allows any employee of a Federal agency acting within the scope of his or her federal employment to obtain Critical Energy Infrastructure Information without going through the process outlined in existing section 388.113(d)(5), as long as the request is approved by a Commission Division Director or higher.

47. The Commission's practice has been for an employee of another agency to sign an Acknowledgement and Agreement, which states that the agency will protect the Critical Energy Infrastructure Information in the same manner as the Commission and will refer any requests for the information to the Commission. The Commission proposes to maintain and codify this practice in the revised CEII regulations in section 388.113(g)(2).

3. Intervenor Requests

48. Individuals in a complaint proceeding or other proceeding to which a right to intervention exists may need CEII to participate in the proceeding. Where a submitter has provided CEII or other non-public information with its filing, existing section 388.112(b)(2)(i) requires a submitter in the context of a proceeding before the Commission to "include a proposed form of a protective agreement with the filing" to facilitate an intervenor's access to information without going through the Critical Energy Infrastructure Information process. Under this provision four categories of information need not be provided subject to such a protective agreement: (1) Landowner lists; (2) privileged information filed under section 380.12(f) or section 380.16(f), which pertain to cultural resources; (3) privileged information filed under section 380.12(m), which pertains to reliability and safety information that must be filed by liquefied natural gas (LNG) facilities; and (4) privileged information filed under section 380.12(o), which pertains to engineering and design material information that must be filed by LNG facilities.

49. However, in *Dominion Cove Point LNG, LP*,[32] the Commission directed a party to release pursuant to a protective agreement LNG safety and engineering information not otherwise available under section 388.112(b)(2)(i). Consistent with that decision, the Commission proposes to amend its regulations to eliminate the current exemptions for LNG information identified under section 388.112(b)(2)(i). This change would leave in place the right of any filer or any person to oppose the disclosure. The Commission proposes to move these requirements to section 388.113(g)(4).

B. Other Considerations for Access to CEII

1. Organizational Requests

50. Existing section 388.113(d)(4)(vi) permits an organization to request CEII for its employees who sign an NDA. With notice to the Commission, the regulation allows the organization to give additional employees access to this CEII, subject to their signing an NDA. The Commission proposes to place a one-year time limit on an organization's ability to add additional employees. After one year from the date of its original request, an organization would have to submit a new CEII request and NDAs pursuant to proposed section 388.113(g)(5)(ii).

2. Timing Requirement

51. An earlier version of the Commission's regulations stated that Critical Energy Infrastructure Information requests would be processed, if possible, within the statutory timeframe for FOIA. The Commission proposes to amend section 388.113(g)(vii) of its regulations to reestablish this requirement for CEII, as the Commission never intended to remove it from the regulations.[33]

3. CEII Combined With Other Protected Information

52. If CEII and proprietary or other protected information are inextricably intertwined, the Commission has historically withheld from disclosure

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[29] For example, FPA section 215A(e) requires the Commission to share "timely actionable information regarding grid security with appropriate key personnel of owners, operators, and users of the critical electric infrastructure." This information may include classified information as well as CEII. Providing notice and seeking a response from a submitter prior to disclosure of this CEII may hinder the Commission's ability to share "timely actionable information."

[30] *See* DOE IG Report at 4–5.

[31] *Critical Energy Infrastructure Information*, Order No. 630, 68 FR 9857 (Mar. 3, 2003), FERC Stats. & Regs. ¶ 31,140 (2003); *order on reh'g*, Order No. 630–A, 68 FR 46,456 (Aug. 6, 2003), FERC Stats. & Regs. ¶ 31,147, at P 57 (2003).

[32] *See Dominion Cove Point LNG, LP*, 147 FERC ¶ 61,202 (2014) (concluding that the protective agreement outlined in section 388.112(b)(2)(i), as opposed to the Critical Energy Infrastructure Information process, was the appropriate mechanism to obtain fourteen identified LNG safety and engineering documents).

[33] This language appears in the April 2007 edition of the Commission's regulations, but does not appear in the April 2008 edition. The preamble to the 2008 regulations does not provide an explanation for the elimination of this provision from the Commission's regulations. Thus, the Commission believes it appropriate to reinstate the requirement.

the intertwined information under FOIA. Consistent with this practice, the Commission proposes to add section 388.113(g)(5)(ix) to clarify that the Commission's CEII regulations should not be construed to require the release of proprietary information, personal information, cultural resource information and other comparable data protected by statute or regulation, or any privileged or otherwise non-public information, including information protected by the deliberative process.

4. CEII Coordinator

53. Under section 375.313, the Commission has delegated to the Coordinator certain authority to address CEII matters. The Commission proposes to amend subsection 375.313(b) to make clear that the Coordinator has designation authority consistent with the FAST Act, and to add a subsection to make clear that the Coordinator has the authority to designate and release information to the public. Moreover, the Commission proposes to change all references in section 375.313 from Critical Energy Infrastructure Information to the acronym CEII.

V. Information Collection Statement

54. The Paperwork Reduction Act and Office of Management and Budget's (OMB) implementing regulations require OMB to review and approve certain information collection requirements imposed by agency rule.[34] This Notice of Proposed Rulemaking does not impose any additional information collection requirements.[35] Therefore, the information collection regulations do not apply to this Notice of Proposed Rulemaking.

VI. Environmental Analysis

55. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[36]

56. The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural, or that do not substantially change the effect of the regulations being amended.[37] The actions here fall within this categorical exclusion in the Commission's regulations.

VII. Regulatory Flexibility Act Certification

57. The Regulatory Flexibility Act of 1980 (RFA) requires rulemakings to contain either a description and analysis of the effect that the rule will have on small entities or a certification that the rule will not have a significant economic impact on a substantial number of small entities.[38] Rules that are exempt from the notice and comment requirements of section 553(b) of the Administrative Procedure Act are exempt from the RFA requirements. This Notice of Proposed Rulemaking concerns rules of agency procedure and, therefore, an analysis under the RFA is not required.[39]

VIII. Public Comments

58. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due August 19, 2016. Comments must refer to Docket No. RM16–15–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

59. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov*. The Commission accepts most standard word processing formats. Information created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

60. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

61. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

IX. Document Availability

62. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

63. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field.

64. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov*, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov*.

List of Subjects

18 CFR Part 375

Authority delegations (Government agencies); Seals and insignia; Sunshine Act.

18 CFR Part 388

Confidential business information; Freedom of information.

By direction of the Commission.

Dated: June 16, 2016.

Kimberly D. Bose,

Secretary.

In consideration of the foregoing, the Commission proposes to amend Parts 375 and 388, Chapter I, Title 18, Code of Federal Regulations, as follows:

PART 375—THE COMMISSION

■ 1. The authority citation for part 375 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352.

■ 2. Amend § 375.313 by:

■ a. Revising the section heading and paragraphs (a) and (b);

■ b. Redesignating paragraphs (c) through (e) as paragraphs (d) through (f) and revising newly redesignated paragraphs (d) through (f); and

■ c. Adding a new paragraph (c).

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[34] 5 CFR 1320.

[35] The current information collection requirements related to requesting access to CEII material are approved by OMB under FERC–603 (OMB Control No. 1902–0197).

[36] *Regulations Implementing the National Environmental Policy Act of 1969*, Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987).

[37] 18 CFR 380.4(a)(2)(ii).

[38] 5 U.S.C. 603 (2012).

[39] 5 U.S.C. 553(b).

The revisions and addition read as follows:

§ 375.313 Delegations to the Critical Energy/Electric Infrastructure Information (CEII) Coordinator.

* * * * *

(a) Receive and review all requests for CEII as defined in § 388.113(c) of this chapter.

(b) Make determinations as to whether particular information fits within the definition of CEII found at § 388.113(c) of this chapter, including designating information, as appropriate.

(c) Make a determination that information designated as CEII should no longer be so designated when the unauthorized disclosure of the information could no longer be used to impair the security or reliability of the bulk-power system or distribution facilities or any other infrastructure.

(d) Make determinations as to whether a particular requester's need for and ability and willingness to protect CEII warrants limited disclosure of the information to the requester.

(e) Establish reasonable conditions on the release of CEII.

(f) Release CEII to requesters who satisfy the requirements in paragraph (d) of this section and agree in writing to abide by any conditions set forth by the Coordinator pursuant to paragraph (e) of this section.

PART 388—INFORMATION AND REQUESTS

■ 3. The authority citation for part 388 is changed to read as follows:

Authority: 5 U.S.C. 301–305, 551, 552 (as amended), 553–557; 42 U.S.C. 7101–7352; 16 U.S.C. 824(o–l).

■ 4. Amend § 388.112 by revising the section heading and paragraphs (a), (b)(1), (b)(2)(i), (b)(2)(vi), (c)(1), and (d)–(e) to read as follows:

§ 388.112 Requests for privileged treatment for documents submitted to the Commission.

(a) *Scope.* By following the procedures specified in this section, any person submitting a document to the Commission may request privileged treatment for some or all of the information contained in a particular document that it claims is exempt from the mandatory public disclosure requirements of the Freedom of Information Act, 5 U.S.C. 552 (FOIA), and should be withheld from public disclosure. For the purposes of the Commission's filing requirements, non-CEII subject to an outstanding claim of exemption from disclosure under FOIA will be referred to as privileged material. The rules governing CEII are contained in 18 CFR 388.113.

(b) *Procedures for filing and obtaining privileged material.* (1) General Procedures. A person requesting that material be treated as privileged information must include in its filing a justification for such treatment in accordance with the filing procedures posted on the Commission's Web site at *http://www.ferc.gov.* A person requesting that a document filed with the Commission be treated as privileged in whole or in part must designate the document as privileged in making an electronic filing or clearly indicate a request for such treatment on a paper filing. The cover page and pages or portions of the document containing material for which privileged treatment is claimed should be clearly labeled in bold, capital lettering, indicating that it contains privileged or confidential information, as appropriate, and marked "DO NOT RELEASE." The filer also must submit to the Commission a public version with the information that is claimed to be privileged material redacted, to the extent practicable.

(2) Procedures for Proceedings with a Right to Intervene. * * *

(i) If a person files material as privileged material in a complaint proceeding or other proceeding to which a right to intervention exists, that person must include a proposed form of protective agreement with the filing, or identify a protective agreement that has already been filed in the proceeding that applies to the filed material. This requirement does not apply to material submitted in hearing or settlement proceedings, or if the only material for which privileged treatment is claimed consists of landowner lists or privileged information filed under sections 380.12(f) and 380.16(f) of this chapter.

* * * * *

(vi) For landowner lists, information filed as privileged under sections 380.12(f) and 380.16(f), forms filed with the Commission, and other documents not covered above, access to this material can be sought pursuant to a FOIA request under section 388.108 of this chapter. Applicants are not required under paragraph (b)(2)(iv) of this section to provide intervenors with landowner lists and the other materials identified in the previous sentence.

(c) *Effect of privilege claim.* (1) For documents filed with the Commission:

(i) The documents for which privileged treatment is claimed will be maintained in the Commission's document repositories as non-public until such time as the Commission may determine that the document is not entitled to the treatment sought and is subject to disclosure consistent with section 388.108 of this chapter. By treating the documents as nonpublic, the Commission is not making a determination on any claim of privilege status. The Commission retains the right to make determinations with regard to any claim of privilege status, and the discretion to release information as necessary to carry out its jurisdictional responsibilities.

(ii) The request for privileged treatment and the public version of the document will be made available while the request is pending.

* * * * *

(d) *Notification of request and opportunity to comment.* When a FOIA requester seeks a document for which privilege status has been claimed, or when the Commission itself is considering release of such information, the Commission official who will decide whether to release the information or any other appropriate Commission official will notify the person who submitted the document and give the person an opportunity (at least five calendar days) in which to comment in writing on the request. A copy of this notice will be sent to the requester.

(e) *Notification before release.* Notice of a decision by the Commission, the Chairman of the Commission, the Director, Office of External Affairs, the General Counsel or General Counsel's designee, a presiding officer in a proceeding under part 385 of this chapter, or any other appropriate official to deny a claim of privilege, in whole or in part, will be given to any person claiming that the information is privileged no less than 5 calendar days before disclosure. The notice will briefly explain why the person's objections to disclosure are not sustained by the Commission. A copy of this notice will be sent to the FOIA requester.

* * * * *

■ 5. Revise § 388.113 to read as follows:

§ 388.113 Critical Energy/Electric Infrastructure Information (CEII)

(a) *Scope.* This section governs the procedures for submitting, designating, handling, sharing, and disseminating Critical Energy/Electric Infrastructure Information (CEII) submitted to or generated by the Commission. The Commission reserves the right to restrict access to previously filed information as well as Commission-generated information containing CEII.

(b) *Purpose.* The procedures in this section implement section 215A of the Federal Power Act, and provide a comprehensive overview of the manner in which the Commission will implement the CEII program.

(c) *Definitions.* For purposes of this section: (1) *Critical electric infrastructure information* means information related to critical electric infrastructure, or proposed critical electrical infrastructure, generated by or provided to the Commission or other Federal agency other than classified national security information, that is designated as critical electric infrastructure information by the Commission or the Secretary of the Department of Energy pursuant to section 215A(d) of the Federal Power Act. Such term includes information that qualifies as critical energy infrastructure information under the Commission's regulations. Critical Electric Infrastructure Information is exempt from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552, pursuant to section 215A(d)(1)(A) of the Federal Power Act.

(2) *Critical energy infrastructure information* means specific engineering, vulnerability, or detailed design information about proposed or existing critical infrastructure that:

(i) Relates details about the production, generation, transportation, transmission, or distribution of energy;

(ii) Could be useful to a person in planning an attack on critical infrastructure;

(iii) Is exempt from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552, pursuant to section 215A(d)(1)(A) of the Federal Power Act; and

(iv) Does not simply give the general location of the critical infrastructure.

(3) *Critical electric infrastructure* means a system or asset of the bulk-power system, whether physical or virtual, the incapacity or destruction of which would negatively affect national security, economic security, public health or safety, or any combination of such matters.

(4) *Critical infrastructure* means existing and proposed systems and assets, whether physical or virtual, the incapacity or destruction of which would negatively affect security, economic security, public health or safety, or any combination of those matters.

(d) *Criteria and Procedures for determining what constitutes CEII.* The following criteria and procedures apply to information labeled as CEII:

(1) For information submitted to the Commission:

(i) A person requesting that information submitted to the Commission be treated as CEII must include with its submission a justification for such treatment in accordance with the filing procedures posted on the Commission's Web site at *http://www.ferc.gov.* The justification must provide how the information, or any portion of the information, qualifies as CEII, as the terms are defined in paragraphs (c)(1) and (2) of this section. The submission must also include a clear statement of the date the information was submitted to the Commission, how long the CEII designation should apply to the information and support for the period proposed. Failure to provide the justification or other required information could result in denial of the designation and release of the information to the public.

(ii) In addition to the justification required by paragraph (d)(1)(i) of this section, a person requesting that information submitted to the Commission be treated as CEII must clearly label the cover page and pages or portions of the information for which CEII treatment is claimed in bold, capital lettering, indicating that it contains CEII, as appropriate, and marked "DO NOT RELEASE." The submitter must also segregate those portions of the information that contain CEII (or information that reasonably could be expected to lead to the disclosure of the CEII) wherever feasible. The submitter must also submit to the Commission a public version with the information where CEII is redacted, to the extent practicable.

(iii) If a person files material as CEII in a complaint proceeding or other proceeding to which a right to intervention exists, that person must include a proposed form of protective agreement with the filing, or identify a protective agreement that has already been filed in the proceeding that applies to the filed material.

(iv) The information for which CEII treatment is claimed will be maintained in the Commission's files as non-public until such time as the Commission may determine that the information is not entitled to the treatment sought. By treating the information as non-public, the Commission is not making a determination on any claim of CEII status. The Commission retains the right to make determinations with regard to any claim of CEII status, and the discretion to release information as necessary to carry out its jurisdictional responsibilities. Although unmarked information may be eligible for CEII treatment, the Commission intends to treat information as CEII only if it is properly designated as CEII pursuant to Commission regulations.

(v) The Commission will evaluate whether the submitted information or portions of the information are covered by the definitions in paragraphs (c)(1) and (2) of this section prior to making a designation as CEII.

(vi) Subject to the exceptions set forth in section 388.113(f)(5), when a CEII requester seeks information for which CEII status has been claimed, or when the Commission itself is considering release of such information, the Commission official who will decide whether to release the information or any other appropriate Commission official will notify the person who submitted the information and give the person an opportunity (at least five calendar days) in which to comment in writing on the request. A copy of this notice will be sent to the requester. Notice of a decision by the Commission, or the CEII Coordinator to make a limited release of CEII, will be given to any person claiming that the information is CEII no less than five calendar days before disclosure. The notice will briefly explain why the submitter's objections to disclosure are not sustained by the Commission. Where applicable, a copy of this notice will be sent to the CEII requester.

(2) For Commission-generated information, after consultation with the Office Director for the office that created the information, or the Office Director's designee, the Coordinator will designate the material as CEII after determining that the information or portions of the information are covered by the definitions in paragraphs (c)(1) and (2) of this section. Commission-generated CEII shall include clear markings to indicate the information is CEII and the date of the designation.

(3) For Commission-generated information, the Commission will segregate non-CEII from CEII or information that reasonably could be expected to lead to the disclosure of CEII wherever feasible.

(e) *Duration of the CEII designation.* All CEII designations will be subject to the following conditions:

(1) A designation may last for up to a five-year period, unless re-designated. In making a determination as to whether the designation should be extended, the CEII Coordinator will take into account information provided in response to paragraph (d)(1)(i) of this section, and any other information, as appropriate.

(2) A designation may be removed at any time, in whole or in part, if the Commission determines that the unauthorized disclosure of CEII could no longer be used to impair the security or reliability of the bulk-power system

or distribution facilities or any other form of energy infrastructure.

(3) If such a designation is removed, the submitter will receive notice and an opportunity to comment. The CEII Coordinator will notify the person who submitted the document and give the person an opportunity (at least five calendar days) in which to comment in writing prior to the removal of the designation. Notice of a removal decision will be given to any person claiming that the information is CEII no less than 5 calendar days before disclosure. The notice will briefly explain why the person's objections to the removal of the designation are not sustained by the Commission.

(4) Prior to seeking judicial review in district court pursuant to section 215A(d)(11) of the Federal Power Act, an administrative appeal of a determination shall be made to the Commission's General Counsel.

(f) *Voluntary sharing of CEII.* The Commission, taking into account standards of the Electric Reliability Organization, will facilitate voluntary sharing of CEII with, between, and by Federal, state, political subdivision, and tribal authorities; the Electric Reliability Organization; regional entities; information sharing and analysis centers established pursuant to Presidential Decision Directive 63; owners, operators, and users of critical electric infrastructure in the United States; and other entities determined appropriate by the Commission. The process will be as follows:

(1) The Director of any Office of the Commission or his designee that wishes to voluntarily share CEII shall consult with the CEII Coordinator prior to the Office Director or his designee making a determination on whether to voluntarily share the CEII.

(2) Consistent with section 388.113(d) of this Chapter, the Commission retains the discretion to release information as necessary to carry out its jurisdictional responsibilities in facilitating voluntary sharing or, in the case of information provided to other federal agencies, the Commission retains the discretion to release information as necessary for those agencies to carry out their jurisdictional responsibilities.

(3) All entities receiving CEII must execute either a non-disclosure agreement or an acknowledgement and agreement. A copy of each agreement will be maintained by the Office Director with a copy to the CEII Coordinator.

(4) When the Commission voluntarily shares CEII pursuant to this subsection, the Commission may impose additional restrictions on how the information may be used and maintained.

(5) Submitters of CEII shall receive notification of a limited release of CEII no less than 5 calendar days before disclosure, except in instances where voluntary sharing is necessary for law enforcement purposes, to maintain infrastructure security, to address potential threats, or when notice would not be practicable.

(g) *Accessing CEII.*

(1) An owner/operator of a facility, including employees and officers of the owner/operator, may obtain CEII relating to its own facility, excluding Commission-generated information except inspection reports/operation reports and any information directed to the owner-operators, directly from Commission staff without going through the procedures outlined in paragraph (g)(5) of this section. Non-employee agents of an owner/operator of such facility may obtain CEII relating to the owner/operator's facility in the same manner as owner/operators as long as they present written authorization from the owner/operator to obtain such information. Notice of such requests must be given to the CEII Coordinator, who shall track this information.

(2) An employee of a federal agency acting within the scope of his or her federal employment may obtain CEII directly from Commission staff without following the procedures outlined in paragraph (g)(5) of this section. Any Commission employee at or above the level of division director or its equivalent may rule on requests for access to CEII by a representative of a federal agency. To obtain access to CEII, an agency employee must sign an acknowledgement and agreement, which states that the agency will protect the CEII in the same manner as the Commission and will refer any requests for the information to the Commission. Notice of each such request also must be given to the CEII Coordinator, who shall track this information.

(3) A landowner whose property is crossed by or in the vicinity of a project may receive detailed alignment sheets containing CEII directly from Commission staff without submitting a non-disclosure agreement as outlined in paragraph (g)(5) of this section. A landowner must provide Commission staff with proof of his or her property interest in the vicinity of a project.

(4) Any person who is a participant in a proceeding or has filed a motion to intervene or notice of intervention in a proceeding may make a written request to the filer for a copy of the complete CEII version of the document without following the procedures outlined in paragraph (g)(5) of this section. The request must include an executed copy of the applicable protective agreement and a statement of the person's right to party or participant status or a copy of the person's motion to intervene or notice of intervention. Any person may file an objection to the proposed form of protective agreement. A filer, or any other person, may file an objection to disclosure, generally or to a particular person or persons who have sought intervention.

(5) If any requester not described above in paragraph (g)(1)–(4) of this section has a particular need for information designated as CEII, the requester may request the information using the following procedures:

(i) File a signed, written request with the Commission's CEII Coordinator. The request must contain the following:

(A) Requester's name (including any other name(s) which the requester has used and the dates the requester used such name(s)), title, address, and telephone number; the name, address, and telephone number of the person or entity on whose behalf the information is requested;

(B) A detailed Statement of Need, which must state: The extent to which a particular function is dependent upon access to the information; why the function cannot be achieved or performed without access to the information; an explanation of whether other information is available to the requester that could facilitate the same objective; how long the information will be needed; whether or not the information is needed to participate in a specific proceeding (with that proceeding identified); and an explanation of whether the information is needed expeditiously.

(C) An executed non-disclosure agreement as described in paragraph (h)(2) of this section;

(D) A signed statement attesting to the accuracy of the information provided in the request; and

(E) A requester shall provide his or her date and place of birth upon request, if it is determined by the CEII Coordinator that this information is necessary to process the request.

(ii) A requester who seeks the information on behalf of all employees of an organization should clearly state that the information is sought for the organization, that the requester is authorized to seek the information on behalf of the organization, and that all individuals in the organization that have access to the CEII will agree to be bound by a non-disclosure agreement that must be executed.

(iii) After the request is received, the CEII Coordinator will determine if the information is CEII, and, if it is, whether to release the CEII to the requester. The CEII Coordinator will balance the requester's need for the information against the sensitivity of the information. If the requester is determined to be eligible to receive the information requested, the CEII Coordinator will determine what conditions, if any, to place on release of the information.

(iv) If the CEII Coordinator determines that the CEII requester has not demonstrated a valid or legitimate need for the CEII or that access to the CEII should be denied for other reasons, this determination may be appealed to the General Counsel pursuant to section 388.110 of this Chapter. The General Counsel will decide whether the information is properly classified as CEII, which by definition is exempt from release under FOIA, and whether the Commission should in its discretion make such CEII available to the CEII requester in view of the requester's asserted legitimacy and need.

(v) Once a CEII requester has been verified by Commission staff as a legitimate requester who does not pose a security risk, his or her verification will be valid for the remainder of that calendar year. Such a requester is not required to provide detailed information about himself or herself with subsequent requests during the calendar year. He or she is also not required to file a non-disclosure agreement with subsequent requests during the calendar year because the original non-disclosure agreement will apply to all subsequent releases of CEII.

(vi) An organization that is granted access to CEII pursuant to paragraph (g)(5)(ii) of this section may seek to add additional individuals to the non-disclosure agreement within one (1) year of the date of the initial CEII request. Such an organization must provide the names of the added individuals to the CEII Coordinator and certify that notice of each added individual has been given to the submitter. Any newly added individuals must execute a supplement to the original non-disclosure agreement indicating their acceptance of its terms. If there is no written opposition within five (5) days of notifying the CEII Coordinator and the submitter concerning the addition of any newly added individuals, the CEII Coordinator will issue a standard notice accepting the addition of these names to the non-disclosure agreement. If the submitter files a timely opposition with the CEII Coordinator, the CEII Coordinator will issue a formal determination addressing the merits of such opposition. If an organization that is granted access to CEII pursuant to paragraph (g)(5)(ii) of this section wants to add new individuals to its non-disclosure agreement more than one year after the date of its initial CEII request, the organization must submit a new CEII request pursuant to paragraph (g)(5)(ii) of this section and a new non-disclosure agreement for each new individual added.

(vii) The CEII Coordinator will attempt to respond to the requester under this section according to the timing required for responses under the FOIA in section 18 CFR 388.108(c).

(viii) Fees for processing CEII requests will be determined in accordance with section 18 CFR 388.109.

(ix) Nothing in this section should be construed as requiring the release of proprietary information, personally identifiable information, cultural resource information and other comparable data protected by statute or any privileged information, including information protected by the deliberative process.

(h) *Duty to protect CEII.* Unauthorized disclosure of CEII is prohibited.

(1) To ensure that the Commissioners, Commission employees, and Commission contractors protect CEII from unauthorized disclosure, internal controls will describe the handling, marking, and security controls for CEII.

(2) Any individual who requests information pursuant to paragraph (g)(5) of this section must sign and execute a non-disclosure agreement, which indicates the individual's willingness to adhere to limitations on the use and disclosure of the information requested. The non-disclosure agreement will, at a minimum, require the following: CEII will only be used for the purpose for which it was requested; CEII may only be discussed with authorized recipients; CEII must be kept in a secure place in a manner that would prevent unauthorized access; CEII must be destroyed or returned to the Commission upon request; and the Commission may audit the Recipient's compliance with the non-disclosure agreement.

(i) Sanctions. Any officers, employees, or agents of the Commission who knowingly and willfully disclose CEII in a manner that is not authorized under this section will be subject to appropriate sanctions, such as removal from the federal service, or possible referral for criminal prosecution. Commissioners who knowingly and willfully disclose CEII without authorization may be referred to the Department of Energy Inspector General. The Commission will take responsibility for investigating and, as necessary, imposing sanctions on its employees and agents.

[FR Doc. 2016–14761 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–133673–15]

RIN 1545–BN07

Deemed Distributions Under Section 305(c) of Stock and Rights To Acquire Stock; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to a notice of proposed rulemaking (REG–133673–15) that were published in the **Federal Register** on April 13, 2016 (81 FR 21795). The proposed regulations are in regards to deemed distributions of stock and rights to acquire stock. The proposed regulations would resolve ambiguities concerning the amount and timing of deemed distributions that are or result from adjustments to rights to acquire stock.

DATES: Written or electronic comments and requests for a public hearing for the notice of proposed rulemaking published at 81 FR 21795, April 13, 2016 are still being accepted and must be received by July 12, 2016.

FOR FURTHER INFORMATION CONTACT: Maurice M. LaBrie at (202) 317–5322; concerning the proposed regulations under sections 860G, 861, 1441, 1461, 1471, and 1473, Subin Seth, (202) 317–6942; concerning the proposed regulations under section 6045B, Pamela Lew, (202) 317–7053; concerning submission of comments, contact Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking (REG–133673–15) that is subject of this correction is under sections 305 and 1473 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking (REG–133673–15) contains errors that may prove to be misleading and are in need of clarification.

Correction to Publication

Accordingly, the notice of proposed rulemaking (REG–133673–15) that was the subject of FR Doc. 2016–08248 is corrected as follows:

§ 1.305–3 [CORRECTED]

■ 1. On page 21802, first column, fourth line from the bottom of Example 6, the language "accordance with § 1.305–7(c)(4)(ii) and the" is corrected to read "accordance with § 1.305–7(c)(4)(i) and the".

§ 1.305–7 [CORRECTED]

■ 2. On page 21803, third column, second line of Example 3.(ii), the language "§ 1.305–1(d)(5), the holders of the convertible" is corrected to read "§ 1.305–1(d)(4), the holders of the convertible".

§ 1.1473–1 [CORRECTED]

■ 3. On page 21807, third column, in paragraph (d)(7), fifth line from the bottom of the page, the language "beneficial owner or a flow through" is corrected to read "beneficial owner, or a flow through".

Martin V. Franks,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2016–15696 Filed 7–1–16; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2016–0278 FRL–9948–59–Region 6]

Approval and Promulgation of Implementation Plans; Louisiana; Baton Rouge Nonattainment Area; Base Year Emissions Inventory for the 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the State Implementation Plan (SIP) submitted by the Louisiana Department of Environmental Quality (LDEQ) to address the emissions inventory (EI) requirement for the Baton Rouge ozone nonattainment area (BRNA) for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS). The Clean Air Act (CAA) requires an EI for all ozone nonattainment areas. The inventory includes emission data for Nitrogen Oxides (NO_X) and Volatile Organic Compounds (VOCs). EPA is approving the revisions pursuant to section 110 and part D of the CAA and EPA's regulations.

DATES: Written comments should be received on or before August 4, 2016.

ADDRESSES: Submit your comments, identified by EPA–R06–OAR–2016–0278, at *http://www.regulations.gov* or via email to *salem.nevine@epa.gov.* For additional information on how to submit comments see the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Nevine Salem, (214) 665–7222, *salem.nevine@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Rules and Regulations section of this **Federal Register**, the EPA is approving the State's SIP submittal as a direct rule without prior proposal because the Agency views this as noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If the EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule which is located in the Rules and Regulations section of this **Federal Register**.

Dated: June 22, 2016.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2016–15743 Filed 7–1–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2016–0002; Internal Agency Docket Nos. FEMA–B–1051 and 1060]

Proposed Flood Elevation Determinations for Will County, Illinois, and Incorporated Areas; Withdrawal

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is withdrawing its proposed rule concerning proposed flood elevation determinations for Will County, Illinois, and Incorporated Areas.

DATES: The proposed rules published on May 26, 2009 and July 2, 2009 (74 FR 24738 and 74 FR 31656), are withdrawn effective July 5, 2016.

ADDRESSES: You may submit comments, identified by Docket Nos. FEMA–B–1051 and 1060 to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;*

SUPPLEMENTARY INFORMATION: On May 26, 2009 and July 2, 2009, FEMA published documents proposing flood elevation determinations along one or more flooding sources in City of Joliet, Unincorporated Areas of Will County, and the Villages of Channahon, Frankfort and Manhattan, Illinois (74 FR 24738 at 24741 and 74 FR 31656 at 31658). FEMA is withdrawing the proposed rules because FEMA has or will be issuing a Revised Preliminary Flood Insurance Rate Map, and if necessary a Flood Insurance Study report, featuring updated flood hazard information. A Notice of Proposed Flood Hazard Determinations will be published in the **Federal Register** and in the affected community's local newspaper following issuance of the Revised Preliminary Flood Insurance Rate Map.

Authority: 42 U.S.C. 4104; 44 CFR 67.4.

Dated: May 19, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2016–15747 Filed 7–1–16; 8:45 am]

BILLING CODE 9110–12–P

Notices

Federal Register
Vol. 81, No. 128
Tuesday, July 5, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Request for Nominations of Members for the National Agricultural Research, Extension, Education, and Economics Advisory Board and Specialty Crop Committee

AGENCY: Research, Education, and Economics, USDA.

ACTION: Solicitation for membership.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App., the United States Department of Agriculture announces the solicitation for nominations to fill vacancies on the National Agricultural Research, Extension, Education, and Economics Advisory Board and its subcommittees. There are 7 vacancies on the NAREE Advisory Board, 3 vacancies on the Specialty Crop Committee, 4 vacancies on the National Genetics Advisory Council, and 6 vacancies on the Citrus Disease Committee.

DATES: All nomination materials should be mailed in a single, complete package and postmarked by July 29, 2016.

ADDRESSES: The nominee's name, resume or CV, completed Form AD–755, and any letters of support must be submitted via one of the following methods:

(1) Email to *nareee@ars.usda.gov;* or

(2) By mail delivery service to Thomas Vilsack, Secretary, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250, Attn: NAREEE Advisory Board, Room 332A, Whitten Building.

FOR FURTHER INFORMATION CONTACT: Michele Esch, Director, National Agricultural Research, Extension, Education, and Economics Advisory Board, 1400 Independence Avenue SW., Room 332A, The Whitten Building, Washington, DC 20250–2255, telephone: 202–720–3684; fax: 202–720–6199; email: *nareeeab@ars.usda.gov.* Committee Web site: *www.nareeeab.ree.usda.gov.*

SUPPLEMENTARY INFORMATION:

Instructions for Nominations

Nominations are solicited from organizations, associations, societies, councils, federations, groups, and companies that represent a wide variety of food and agricultural interests throughout the country. Nominations for one individual who fits several of the categories listed above, *or* for more than one person who fits one category, will be accepted.

In your nomination letter, please indicate the specific membership category for each nomine if applying for the NAREEE Advisory Committee and also specify what committee(s) you are sending your nomination is for. Each nominee must submit form AD–755, "Advisory Committee Membership Background Information" (which can be obtained from the contact person below or from: *http://www.ocio.usda.gov/sites/default/files/docs/2012/AD-755_Master_2012_508%20Ver.pdf*). All nominees will be vetted before selection.

Nominations are open to all individuals without regard to race, color, religion, sex, national origin, age, mental or physical handicap, marital status, or sexual orientation. To ensure the recommendation of the Advisory Board take into account the needs of the diverse groups served by the USDA, membership shall include, to the extent practicable, individuals with demonstrated ability to represent the needs of all racial and ethnic groups, women and men, and persons with disabilities.

Please note that registered lobbyist and individuals already serving another USDA Federal Advisory Committee, are ineligible for nomination.

All nominees will be carefully reviewed for their expertise, leadership, and relevance. All nominees will be vetted before selection.

Appointments to the National Agricultural Research, Extension, Education, and Economics Advisory Board and its subcommittees will be made by the Secretary of Agriculture.

National Agricultural Research, Extension, Education, and Economics Advisory Board

The National Agricultural Research, Extension, Education, and Economics Advisory Board was established in 1996 via section 1408 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3123) to provide advice to the Secretary of Agriculture and land-grant colleges and universities on top priorities and policies for food and agricultural research, education, extension, and economics. Section 1408 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 was amended by the Farm Security and Rural Investment Act of 2002 to reduce the number of members on the National Agricultural Research, Extension, Education, and Economics Advisory Board to 25 members and required the Board to also provide advice to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies of the Committee on Appropriations of the House of Representatives, and the Subcommittee on Agriculture, Rural Development and Related Agencies of the Committee on Appropriations of the Senate.

Since the Advisory Boards inception by congressional legislation in 1996, each member has represented a specific category related to farming or ranching, food production and processing, forestry research, crop and animal science, land-grant institutions, non-land grant college or university with a historic commitment to research in the food and agricultural sciences, food retailing and marketing, rural economic development, and natural resource and consumer interest groups, among many others. The Board was first appointed by the Secretary of Agriculture in September 1996 and one-third of its members were appointed for a one, two, and three-year term, respectively. The terms for 7 members who represent specific categories will expire September 30, 2016. Nominations for a 3-year appointment for these 7 vacant categories are sought. All nominees will be carefully reviewed for their expertise, leadership, and relevance to a category.

The 7 slots to be filled are:

Category F. National Food Animal Science Society
Category G. National Crop, Soil, Agronomy, Horticulture, or Weed Science Society
Category L. 1890 Land-Grant Colleges and Universities
Category M. 1994 Equity in Education-Land Grant Institutions
Category P. American Colleges of Veterinary Medicine
Category T. Rural Economic Development
Category U. National Consumer Interest Group

Specialty Crop Committee

The Specialty Crop Committee was created as a subcommittee of the National Agricultural Research, Extension, Education, and Economics Advisory Board in 2004 in accordance with the Specialty Crops Competitiveness Act of 2004 under title III, section 303 of Public Law 108–465. The committee was formulated to study the scope and effectiveness of research, extension, and economics programs affecting the specialty crop industry. The legislation defines "specialty crops" as fruits, vegetables, tree nuts, dried fruits and nursery crops (including floriculture). The Agricultural Act of 2014 further expanded the scope of the Specialty Crop Committee to provide advice to the Secretary of Agriculture on the relevancy review process of the Specialty Crop Research Initiative, a granting program of the National Institute of Food and Agriculture.

Members should represent the breadth of the specialty crop industry. 6 members of the Specialty Crop Committee are also members of the National Agricultural Research, Extension, Education, and Economics Advisory Board and 6 members represent various disciplines of the specialty crop industry.

The terms of 3 members will expire on September 30, 2015. The Specialty Crop Committee is soliciting nominations to fill 3 vacant positions. Appointed members will serve 2–3 years with their terms expiring in September 2017 or 2018.

National Genetic Resources Advisory Council

The National Genetic Resources Advisory Council was re-established in 2012 as a permanent subcommittee of the National Agricultural Research, Extension, Education, and Economics (NAREEE) Advisory Board to formulate recommendations on actions and policies for the collection, maintenance, and utilization of genetic resources; to make recommendations for coordination of genetic resources plans of several domestic and international organizations; and to advise the Secretary of Agriculture and the National Genetic Resources Program of new and innovative approaches to genetic resources conservation. The National Genetic Resources Advisory Council will also advise the department on developing a broad strategy for maintaining plant biodiversity available to agriculture, and strengthening public sector plant breeding capacities.

The National Genetic Resources Advisory Council membership is required to have two-thirds of the appointed members from scientific disciplines relevant to the National Genetic Resources Program including agricultural sciences, environmental sciences, natural resource sciences, health sciences, and nutritional sciences; and one-third of the appointed members from the general public including leaders in fields of public policy, trade, international development, law, or management.

The terms of 4 members of the National Genetic Resources Advisory Council will expire on September 30, 2016. We are seeking nominations for a 4-year appointment effective October 1, 2016 through September 30, 2020. The 4 slots to be filled are to be composed of 3 scientific members and 1 general public member.

Citrus Disease Subcommittee

The Citrus Disease Subcommittee was established by the Agricultural Act of 2014 (Sec. 7103) to advise the Secretary of Agriculture on citrus research, extension, and development needs, engage in regular consultation and collaboration with USDA and other organizations involved in citrus, and provide recommendations for research and extension activities related to citrus disease. The Citrus Disease Subcommittee will also advise the Department on the research and extension agenda of the Emergency Citrus Disease Research and Extension Program, a granting program of the National Institute of Food and Agriculture.

The subcommittee is composed of 9 members who *must* be a producer of citrus with representation from the following States: Three members from Arizona or California, five members from Florida, and one member from Texas.

The terms of 6 Citrus Disease Subcommittee will expire on September 30, 2015. The Citrus Disease Subcommittee is soliciting nominations to fill 6 vacant positons for membership; 4 positions are to represent Florida and 2 positions are to represent California. Appointed members will serve 2–3 years with their terms expiring in September 2017 or 2018.

Done at Washington, DC, this 28 day of June 2016.

Ann Bartuska,

Deputy Under Secretary, Research, Education, and Economics.

[FR Doc. 2016–15851 Filed 7–1–16; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; 2017 Economic Census

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before September 6, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Kevin Deardorff, U.S. Census Bureau, Economy Wide Statistics Division, Room 8K154, 4600 Silver Hill Road, Washington, DC 20233, telephone (301) 763–6033, or via the Internet at *Kevin.E.Deardorff@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau is the preeminent collector and provider of timely, relevant, and quality data about the people and economy of the United States. Economic data are the Census Bureau's primary program commitment during nondecennial census years. The Economic Census, conducted under authority of Title 13 United States Code, is the U.S. Government's official five-year measure of American business and the economy. It features the primary source of facts about the structure and functioning of the Nation's economy and features unique industry and geographic detail. Economic census statistics serve as part of the framework for the national accounts and provide essential information for government, business, and the public.

The 2017 Economic Census covering the Mining; Utilities; Construction; Manufacturing; Wholesale Trade; Retail Trade; Transportation and Warehousing; Information; Finance and Insurance; Real Estate and Rental and Leasing; Professional, Scientific and Technical Services; Management of Companies and Enterprises; Administrative and Support and Waste Management and Remediation; Educational Services; Health Care and Social Assistance; Arts, Entertainment, and Recreation; Accommodation and Food Services; Other Services (except Public Administration) Sectors (as defined by the North American Industry Classification System (NAICS)) will measure the economic activity of more than 7 million employer establishments. The information collected from establishments in these sectors of the economic census will produce basic statistics by industry for number of establishments, value of shipments/receipts/revenue/sales, payroll, and employment. It also will yield a variety of industry-specific statistics, including materials consumed, detailed supplies and fuels consumed, electric energy consumed, depreciable assets, selected purchased services, inventories, and capital expenditures, value of shipments/receipts/revenue/sales by product line as defined by the North American Product Classification System (NAPCS), type of operation, size of establishments, and other industry-specific measures.

Respondent burden will be reduced by using a response driven electronic reporting instrument that includes skip patterns and will display survey paths specific to the establishment's kind of business.

II. Method of Collection

Establishments in the Economic Census will be selected from the Census Bureau's Business Register. The Census Bureau's Business Register provides a current and comprehensive database of U.S. business establishments and companies for statistical program use. To be eligible for selection, an establishment will be required to satisfy the following conditions: (i) It must be classified in one of the sectors listed above; (ii) it must be an active operating establishment of a multi-establishment firm (*i.e.*, a firm that operates at more than one physical location), or it must be a single-establishment firm with payroll (*i.e.*, a firm operating at only one physical location); and (iii) it must be located in one of the 50 states, offshore areas, or the District of Columbia. Initial contact with respondents will be a mailed letter directing them to report online. No form will be mailed. The sampling procedure will distinguish the following groups of establishments for collection:

1. Establishments of Multi-Establishment Firms

Selection procedures will assign all active establishments of multi-establishment firms to the mail component of the universe, except for those in industries classified as consolidated reporters. In these selected industries, where activities are not easily attributable to individual locations or establishments, firms will be asked to report their basic data for several establishments at a nation-wide level on an electronic consolidated report path(s).

2. Single-Establishment Firms With Payroll

All single-establishment firms having 2017 payroll (from Federal administrative records) will be included in the sampling frame. We will use a NAICS-by-state stratified sample design for selecting a sample of single-establishment firms. The largest single-establishment firms (based on 2017 payroll) will be selected with certainty. Using a NAICS-by-state stratified sample should produce reliable estimates for various characteristics at detailed NAICS-by-state levels.

The remaining single-establishment firms with payroll that are not selected into the sample will be represented in the Economic Census by data from Federal administrative records, or by weighting the responses of the sampled establishments. Additionally, some of these single-establishment firms not selected into the sample may be requested to respond to a short questionnaire to verify or confirm that the establishments are classified in the correct NAICS industry.

III. Data

OMB Control Number: 0607–XXXX.

Electronic ID Path(s): The paths in the electronic instrument used to collect information are tailored to specific industries or groups of industries. The Electronic Path ID's are too numerous to list individually in this notice.

Type of Review: Regular submission.

Affected Public: State or local governments, businesses, or other for profit or non-profit institutions or organizations.

Estimated Number of Respondents: 4,423,783—see Table 1 for detail.

Estimated Time per Response: See Table 1 for detail.

Estimated Total Annual Burden Hours: 6,832,591—see Table 1 for detail.

Estimated Total Annual Cost: $0.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C. Section 131.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: June 29, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

Table 1: Estimated 2017 Census Sample Sizes by Sector

Sector	Trade	Total Estabs	Estimated Number of Respondents	Multi Estabs	Single-Establishments						Estimated Time Per Response/ Hour	Estimated Total Annual Burden Hours
						Selected			Not Selected			
						Long "Forms"						
				Total	Univ	Cert	NonCert	Total	Total (2)	Class (1) "Forms"		
21	Mining (3)	28,474	23,890	9,179	19,295	11,053	1,237	12,290	7,005	2,421	4.0	95,560
22	Utilities (3)	18,042	18,042	13,174	4,868	4,868	0	4,868	0	0	2.2	39,692
23	Construction	643,514	215,108	18,549	624,965	33,365	89,882	123,247	501,718	73,312	2.3	494,748
31	Manufacturing	284,418	230,608	58,144	226,274	112,810	17,039	129,849	96,425	42,615	5.6	1,291,405
42	Wholesale Trade	400,444	400,444	133,667	266,777	266,777	0	266,777	0	0	1.3	520,577
44	Retail Trade	1,039,621	742,489	446,413	593,208	159,195	58,692	217,887	375,321	78,189	1.0	742,489
48	Transportation and Warehousing	217,107	169,714	56,205	160,902	67,465	19,386	86,851	74,051	26,658	4.4	746,742
51	Information (3)	132,838	108,217	70,202	62,636	28,362	5,429	33,791	28,845	4,224	1.4	151,504
52	Finance and Insurance (3)	464,674	367,924	249,745	214,929	101,367	12,816	114,183	100,746	3,996	1.5	551,886
53	Real Estate and Rental and Leasing	353,421	222,181	96,941	256,480	32,931	33,407	66,338	190,142	58,902	1.0	222,181
54	Professional, Scientific and Technical Services	820,435	380,653	112,276	708,159	101,472	65,172	166,644	541,515	101,733	1.0	380,653
55	Management of Companies and Enterprises	68,963	68,963	65,477	3,486	3,486	0	3,486	0	0	1.9	131,030
56	Administrative and Support and Waste	387,120	182,388	78,649	308,471	49,541	33,044	82,585	225,886	21,154	1.0	182,388
61	Educational Services	68,482	38,087	7,620	60,862	11,776	8,729	20,505	40,357	9,962	0.7	26,661
62	Health Care and Social Assistance	833,364	441,928	235,422	597,942	120,226	46,929	167,155	430,787	39,351	1.0	441,928
71	Arts, Entertainment, and Recreation	120,359	75,571	13,963	106,396	34,025	10,180	44,205	62,191	17,403	1.0	75,571
72	Accommodation and Food Services	668,341	462,367	192,107	476,234	169,848	24,058	193,906	282,328	76,354	1.0	462,367
81	Other Services (except Public Admin.)	526,210	275,209	76,542	449,668	106,194	44,984	151,178	298,490	47,489	1.0	275,209
Totals		7,075,827	4,423,783	1,934,275	5,141,552	1,414,761	470,984	1,885,745	3,255,807	603,763		6,832,591

Notes: (1) Class "forms" counts are included in the "Not Selected" total

(2) Federal administrative records

(3) Approximately 7% of Multi-establishments in selected industries classifed in the Mining sector and approximately 4% of selected industries classified in Utilites, Information, and Finance and Insurance sectors report basic data for several establishments at a nation-wide level on consolidated report paths(s) to ease burden.

[FR Doc. 2016–15787 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; 2017 Economic Census of Island Areas

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before September 6, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Kevin Deardorff, U.S. Census Bureau, Economy Wide Statistics Division, Room 8K154, 4600 Silver Hill Road, Washington, DC 20233, telephone (301) 763–6033, or via the Internet at *Kevin.E.Deardorff@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Economic Census of Island Areas, conducted under authority of Title 13, United States Code (U.S.C.), Section 131, is the primary source of facts about the structure and functioning of the U.S. economy, including Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the U.S. Virgin Islands, and American Samoa, collectively referred to as Island Areas. The Economic Census of Island Areas, is the primary source of facts about each of the island areas' economies. Economic Census of Island Areas statistics serve to benchmark estimates of local net income and gross domestic product, and provide essential information for government (Federal and local), businesses, and the general public.

The 2017 Economic Census of Island Areas will cover the following sectors as defined by the North American Industry Classification System (NAICS): Mining; Utilities; Construction; Manufacturing; Wholesale and Retail Trades; Transportation and Warehousing; Information; Finance and Insurance; Real Estate and Rental and Leasing; Professional, Scientific, and Technical Services; Management of Companies and Enterprises; Administrative and Support and Waste Management and Remediation Services; Educational Services; Health Care and Social Assistance; Arts, Entertainment, and Recreation; Accommodation and Food Services; and Other Services (except Public Administration). This scope is roughly equivalent to that of the stateside Economic Census. Due to concerns about the completeness of the universe for collection, the Economic Census of Island Areas does not collect data on Scheduled Air Transportation (NAICS 4811) or Business, Professional, Labor, Political, and Similar Organizations (NAICS 8139). The Economic Census of Island Areas is the only source of economic data collected for the Island Areas.

The information collected will produce statistics by kind of business on the number of establishments, sales, value of shipments, receipts, revenue, payroll, and employment. The Economic Census of Island Areas will also yield a variety of industry-specific statistics, including sales/receipts by commodity/merchandise/receipt lines, sales/value of shipments by class of customer, and number of hotel rooms. While the Economic Census of Island Areas collects the same sector level data as the Economic Census, the data published are at a less detailed NAICS level with some additional exclusions.

Data collection for the 2017 Economic Census of Island Areas will begin in January of 2018 and will closeout in October of 2018. In an effort to reduce respondent burden, processing time, and cost, the 2017 Economic Census of Island Areas is aiming to increase data collection through the use of electronic reporting tools.

II. Method of Collection

The 2017 Economic Census of Island Areas will be conducted using electronic reporting instrument procedures with a follow-up mailout of a paper questionnaire. Establishments will be selected from the Census Bureau's Business Register. The Census Bureau's Business Register provides a current and comprehensive database of U.S. business establishments and companies for statistical program use. An establishment will be included in the 2017 Economic Census of Island Areas if: (a) It is engaged in any of the sectors within the scope of the census listed above; (b) it is an active operating establishment with payroll; and (c) it is located in Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the U.S. Virgin Islands, or American Samoa.

III. Data

OMB Control Number: 0607–XXXX.

Questionnaire Number(s): Electronic Path ID(s): The questionnaires and paths in the electronic instrument used to collect information in the Islands Areas are tailored to specific industries or groups of industries. Puerto Rico questionnaires and electronic instruments are available in English as well as Spanish.

Questionnaire No. and electronic path ID	Island area	Trade
2101T	Puerto Rico	Utilities, Transportation, and Warehousing.
2102T	Puerto Rico	Utilidades, Transportacion y Almacenaje.
2103T	Selected U.S. Territories	Utilities, Transportation, and Warehousing.
2104T	American Samoa	Utilities, Transportation, and Warehousing.
2301T	Puerto Rico	Construction.
2302T	Puerto Rico	Industrias de Construccion.
2303T	Selected U.S. Territories	Construction.
2304T	American Samoa	Construction.
3101T	Puerto Rico	Manufacturing.
3102T	Puerto Rico	Manufactura.
3103T	Selected U.S. Territories	Manufacturing.
3104T	American Samoa	Manufacturing.
4201T	Puerto Rico	Wholesale Trade.
4202T	Puerto Rico	Comercio al Poy Mayor.
4203T	Selected U.S. Territories	Wholesale Trade.
4204T	American Samoa	Wholesale Trade.
4401T	Puerto Rico	Retail Trade.
4402T	Puerto Rico	Comercio al Detal.
4403T	Selected U.S. Territories	Retail Trade.
4404T	American Samoa	Retail Trade.
5101T	Puerto Rico	Services.
5102T	Puerto Rico	Servicios.
5103T	Selected U.S. Territories	Services.
5104T	American Samoa	Services.
5201T	Puerto Rico	Finance, Insurance, Real Estate, Rental, and Leasing.
5202T	Puerto Rico	Finanzas y Seguros, Bienes Raices, Alquiler y Arrendamiento.
5203T	Selected U.S. Territories	Finance, Insurance, Real Estate, Rental, and Leasing.
5204T	American Samoa	Finance, Insurance, Real Estate, Rental, and Leasing.
7201T	Puerto Rico	Accommodation Services.
7202T	Puerto Rico	Servicios de Alojamiento.
7203T	Selected U.S. Territories	Accommodation Services.
7204T	American Samoa	Accommodation Services.

Type of Review: Regular submission.

Affected Public: Local governments, businesses, and other for profit or nonprofit institutions or organizations.

Estimated Number of Respondents: 52,970 (Puerto Rico: 45,000; Guam: 3,400; Commonwealth of the Northern Mariana Islands: 1,400; U.S. Virgin Islands: 2,700; American Samoa: 470).

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 52,970 hours.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13, U.S.C., Section 131 and 191.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: June 29, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–15786 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: U.S. Census Bureau.

Title: Address Canvassing Testing.

OMB Control Number: 0607–XXXX.

Form Number(s):

DF–31DA(E/S) Confidentiality Notice.
LiMA Screenshots.

Type of Request: Regular Submission.

Number of Respondents: 86,250.

Average Hours per Response: 5 minutes per Household.

Burden Hours: 7,188.

Needs and Uses: During the years preceding the 2020 Census, the Census Bureau will pursue its commitment to reduce the costs of conducting a decennial census, while maintaining our commitment to quality. The goal of Reengineering Address Canvassing is to ensure an accurate address frame is developed utilizing innovative methodologies and data for updating the Master Address File (MAF)/Topologically Integrated Geographic Encoding and Referencing (TIGER) System throughout the decade. The Census Bureau plans to test Address Canvassing during the Fall of 2016 in the Address Canvassing Test, and in the Spring of 2017 as part of the 2017 Puerto Rico Census Test. Both tests will include two major components of the reengineered Address Canvassing operation: In-Office Address Canvassing and In-Field Address Canvassing. The purpose of the tests is to determine the accuracy and feasibility of some of the planned innovations for Address Canvassing. The Census Bureau believes that there are other means for accomplishing the address list updates and determining which areas have housing changes without canvassing every single block in the field just before the census as was done in previous censuses. These tests will examine these new methods, which will allow decisions to be made about their feasibility for use within the decennial census.

The following objectives are crucial to a successful Address Canvassing Test and 2017 Puerto Rico Census Test:

- Implementing all planned 2020 Census In-Office Address Canvassing processes, including Interactive Review (IR), Active Block Resolution (ABR), MAF Updating and Identification of the In-Field Address Canvassing workload.
- Evaluating the effectiveness of online training for Field Supervisors and Field Representatives.
- Measuring the effectiveness of In-Office Address Canvassing through In-Field Address Canvassing.
- Integrating multiple information technology applications to create one seamless operational data collection, control and management system.

The Address Canvassing Test occurs in two sites within the continental United States. Each site is comprised of 4,000 blocks with up to 125,000 addresses in each site. All living quarters in the test sites are included in the In-Office Address Canvassing workload, as well as the In-Field Address Canvassing workload. For the In-Field Address Canvassing data collection, listers will knock on every door to ask residents about their living quarters. In addition to the Address Canvassing Test, the Census Bureau will also test the Address Canvassing operation as part of the 2017 Puerto Rico Census Test. This information is new compared to the information that was included in the **Federal Register** Notice for the Address Canvassing Test. The addition of the 2017 Puerto Rico Census Test Address Canvassing necessitated a name change for this package to "Address Canvassing Testing" from the "Address Canvassing Test" that appeared in the earlier **Federal Register** Notice. The Address Canvassing operations in the 2017 Puerto Rico Census Test will occur in the winter of 2017 and in the sites selected for the 2017 Puerto Rico Census Test. This universe consists of an estimated 95,000 housing units in the selected areas. The methodology and test objectives for the Address Canvassing operation in the 2017 Puerto Rico Census Test are the same as the Address Canvassing Test.

Supporting Documents About the 2020 Census Design and the Address Canvassing Test Objectives

We are submitting with the package the following documents with the purpose stated:

1. The 2020 Census Operational Plan documents at a high-level the objectives for the census tests already completed, as well as those planned for the future. This document shows the current planned design of the 2020 Census and identifies design decisions made, as well as remaining decisions to be made using census test results. *https://www.census.gov/programs-surveys/decennial-census/2020-census/planning-management/memo-series/2020-memo-2015_02.html.*

2. The 2020 Census Detailed Operational Plan for the Address Canvassing Operation complements the U.S. Census Bureau's 2020 Census Operational Plan. This document describes the objectives and procedures for all aspects of the Address Canvassing program, including a description of the major tasks involved in the implementation, the overall program workflow, and the overall resources needed to support the effort. *https://www.census.gov/programs-surveys/decennial-census/2020-census/planning-management/memo-series/2020-memo-2015_04.html.*

3. The 2020 Census Research and Testing Management Plan defines the high-level research for the life-cycle of the program, thereby providing direction for research and testing activities and for decision-making based on the outcomes. *https://www.census.gov/programs-surveys/decennial-census/2020-census/planning-management/memo-series/2020-memo-2015_03.html.*

In addition, we are submitting planning documents that list our Goals, Objectives, and Success Criteria for the Address Canvassing Test and the 2017 Puerto Rico Census Test, which outlines the research questions related to the design decisions to be made using the results of this test.

Address Canvassing Test—Buncombe County, North Carolina and St. Louis (Part), Missouri

For the Address Canvassing Test, the areas within Buncombe County, North Carolina and St. Louis (part), Missouri were chosen based on a variety of characteristics:

- One site is experiencing population and housing unit growth and contains a mix of urban, suburban and rural territory.
- One site is a city experiencing sustained population decline.
- Both sites contain a mix of address styles, such as city-style addresses (*i.e.*, 101 Main St.), non city-style addresses (*i.e.*, Rural Route 2, Box 12) and location descriptions (*i.e.*, Tan Mobile Home).

- The urban site contains a mix of housing types and conditions, including small and large multi-unit structures, commercial-to-residential conversions, and mixed commercial and residential uses, and residential redevelopment, as well as an area in which housing units are vacant, uninhabitable, and have been demolished.

These characteristics can help the Census Bureau refine its operational plans for the 2020 Census by testing processes and systems in a growth setting as well as processes and systems in an area containing small and large multi-unit structures, commercial-to-residential conversions, mixed commercial and residential uses, and various housing unit status, such as vacant, uninhabitable and demolished.

Buncombe County, North Carolina places and Census designated places (CDP)	St. Louis, Missouri (part) places
Asheville city	St. Louis city.
Biltmore Forest town.	
Black Mountain town	
Montreat town	
Weaverville town	
Woodfin town	
Avery Creek CDP	
Bent Creek CDP	
Fairview CDP	
Royal Pines CDP	
Swannanoa CDP	

All living quarters in the test sites are included in the In-Office Address Canvassing workload, as well as the In-Field Address Canvassing workload. This allows for the comparison of results from both In-Office Address Canvassing and In-Field Address Canvassing to measure the effectiveness of In-Office Address Canvassing procedures and processes.

2017 Puerto Rico Census Test—Carolina, Loíza, and Trujillo Alto Municipios

For the 2017 Puerto Rico Census Test, the areas of Carolina, Loíza, and Trujillo Alto *municipios* were chosen based on a variety of characteristics:

- Site is within the San Juan metropolitan area.
- Site includes anticipated areas of Self Response and Update Enumerate
- Site has a municipio with a mix of address types.

These characteristics can help the Census Bureau refine its operational plans for the 2020 Census by testing processes and systems in an area containing a large variety of address types, and it affords the opportunity to test both Self Response and Update Enumerate. The Self Response areas are where In-Field Address Canvassing will be conducted.

Carolina Municipio Census designated places (CDP)	Loíza Municipio census designated places (CDP)	Trujillo Alto Municipio Census designated places (CDP)
Carolina zona urbana	Loíza zona urbana	Trujillo Alto zona urbana.
	Suárez comunidad	
	Vieques comunidad.	

All living quarters in the test sites are included in the In-Office Address Canvassing workload, as well as in the In-Field Address Canvassing workload. This allows for the comparison of results from both In-Office Address Canvassing and In-Field Address Canvassing to measure the effectiveness of In-Office Address Canvassing procedures and processes.

Address Canvassing

Background

For the 2010 Census, the Address Canvassing field staff, referred to as listers, traversed almost every block in the nation to compare what they observed on the ground to the contents of the Census Bureau's address list. Listers verified or corrected addresses that were on the list, added new addresses to the list, and deleted addresses that no longer existed. Listers also collected map spot locations (*i.e.*, Global Positioning System coordinates) for each structure and added new streets.

In addition to Address Canvassing, the Census Bureau conducted the Group Quarters Validation (GQV) operation after the Address Canvassing operation and prior to enumeration for the 2010 Census. The purpose of the GQV operation was to improve the Group Quarters (GQ) frame. A GQ is a place where people live or stay, in a group living arrangement, that is owned or managed by an entity or organization providing housing and/or services for the residents. This is not a typical household-type living arrangement, and residency is commonly restricted to those receiving specific services. People living in GQs are usually not related to each other. Types of GQs include such places as college residence halls, residential treatment centers, skilled-nursing facilities, group homes, military barracks, correctional facilities, and workers' dormitories. Services offered may include custodial or medical care, as well as other types of assistance.

For the 2010 Census GQV operation, field staff visited a specific address to determine if it was a GQ, a housing unit, a transitory location, a non-residential unit, or if it was nonexistent. If the address was a GQ, the lister conducted an in-person interview with the GQ contact person to determine a type of GQ and collect additional information to plan for enumeration. In support of a more efficient census design strategy, the Census Bureau will not conduct a separate operation to validate GQ information in the 2020 Census. Instead, during the Address Canvassing Test and the 2020 Census, GQ information will be validated during the Address Canvassing operation.

2020 Census Address Canvassing: In-Office Address Canvassing

In-Office Address Canvassing is the process of using empirical geographic evidence (*e.g.*, imagery, comparison of the Census Bureau's address list to partner-provided lists) to assess the current address list and make changes where necessary. This component removes geographic areas from the In-Field Address Canvassing workload based on the determination of address stability. In addition, this component detects and captures change from high quality administrative and third-party data, reducing the In-Field Address Canvassing workload as well.

In-Office Address Canvassing starts with Interactive Review (IR), which is an imagery-based review to assess the extent to which the number of addresses—both housing units and GQs—in the census address list are consistent with the number of addresses visible in current imagery. It also assesses the changes between the current imagery and an older vintage of imagery (around the time of the 2010 Census Address Canvassing).

Results from IR inform the Active Block Resolution (ABR) process, which seeks to research and update areas identified with growth, decline, undercoverage of addresses, or overcoverage of addresses from the comparison of the two different vintages of imagery and counts of addresses in the MAF. In addition to using the results from IR, the ABR process uses other data sources to attempt to resolve the identified issues in the office rather than sending these areas to In-Field Address Canvassing. The other data sources include local Geographic Information Systems (GIS) viewers available online, parcel data from local governments, local files acquired through the U.S. Census Bureau's Geographic Support System (GSS) program, and commercial data. Areas not resolved in the office become the universe of geographic areas for the In-Field Address Canvassing.

2020 Census Address Canvasing: In-Field Address Canvassing

In-Field Address Canvassing is the process of having field staff visit specific geographic areas to identify every place where people could live or stay and compare what they see on the ground to the existing census address list to either verify or correct the address and location information. In general, the field staff will:

- Receive assignments and prepare for work.
- Locate and travel to an assignment.
- Compare what is on the ground to the Census Bureau address list and update it as necessary (add addresses, delete addresses, and correct addresses).
- Update the map as required (update street names, add streets, and collect GPS coordinates).
- Collect GQ information including the GQ type for GQ addresses.
- Mark the assignment as complete and submit the results.
- Receive next assignment until no more assignments exist.

Listers will knock on doors at every structure in an attempt to locate Living Quarters (LQs). If someone answers, the lister will provide a Confidentiality Notice and ask about the address in order to verify or update the information, as appropriate. The listers will then ask if there are any additional LQs in the structure or on the property. If there are additional LQs, the listers will collect/update that information, as appropriate. If listers do not find anyone at home, they will update the address list by observation, as was done in the 2010 Census Address Canvassing. The Census Bureau expects that they would make contact with residents (*i.e.*, someone is at home) approximately 25 percent of the time. Please note, the Address Canvassing Testing FRN incorrectly stated that the Census Bureau expects the listers would make contact with residents 50 percent of the time.

The purpose of the Address Canvassing Operation in the 2020 Census is (1) to deliver a complete and accurate address list and spatial database for enumeration and tabulation, and (2) to determine the type and address characteristics for each living quarter. A complete and accurate address list and map is the cornerstone of a successful census.

The Census Bureau needs to solidify evidence showing whether the strategies being tested can reduce the cost per housing unit during a decennial census, while still providing high quality and accurate census data. The results of this Address Canvassing Test and the 2017 Puerto Rico Census Test will inform decisions that the Census Bureau will make to refine the 2020 Census Operational Plan as well as the 2020 Census Detailed Operational Plan for the Address Canvassing Operation. The results will also help guide the evaluation of additional 2020 Census test results later this decade.

Affected Public: Households/ Individuals.

Frequency: One time.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 United States Code, Sections 141 and 193.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202)395–5806.

Dated: June 28, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–15742 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–041]

Truck and Bus Tires From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination, in Part, and Alignment of Final Determination With Final Antidumping Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of truck and bus tires from the People's Republic of China (PRC). The period of investigation is January 1, 2015, through December 31, 2015. Interested parties are invited to comment on this preliminary determination.

DATES: Effective Date: July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Jennifer Shore or Mark Kennedy, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2778 or (202) 482–7883, respectively.

Alignment of Final Countervailing Duty (CVD) Determination With Final Antidumping Duty (AD) Determination

On the same day the Department initiated this CVD investigation, the Department also initiated an AD investigation of truck and bus tires from the PRC.[1] This CVD investigation and the companion AD investigation cover the same merchandise.

On June 15, 2016, in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (Act), the petitioner[2] requested alignment of the final CVD determination of truck and bus tires from the PRC with the final AD determination of truck and bus tires tires from the PRC. Therefore, in accordance with section 705(a)(1) of the

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[1] *See Truck and Bus Tires from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 81 FR 9428 (February 25, 2016) (*Initiation Notice*). *See also Truck and Bus Tires from the People's Republic of China: Initiation of Antidumping Duty Investigation,* 81 FR 9434 (February 25, 2016).

[2] The petitioner in this investigation is the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC (the "USW").

Act and 19 CFR 351.210(b)(4), we are aligning the final CVD determination with the final PRC AD determination. Consequently, the final CVD determination will be issued on the same date as the PRC AD determination, which is currently scheduled to be issued no later than November 9, 2016.

Scope of the Investigation

The product covered by this investigation is truck and bus tires from the PRC. For a full description of the scope of the investigation, *see* Appendix I.

Scope Comments

Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice*. For discussion of those comments, *see* the Preliminary Decision Memorandum.[3]

Methodology

The Department is conducting this CVD investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy (*i.e.,* a financial contribution by an "authority" that gives rise to a benefit to the recipient) and that the subsidy is specific.[4] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

In making this preliminary determination, the Department relied, in part, on facts otherwise available, with the application of adverse inferences.[5] For further information, *see* "Use of Facts Otherwise Available and Application of Adverse Inferences" in the accompanying Preliminary Decision Memorandum.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Preliminary Determination of Critical Circumstances, in Part

In accordance with section 703(e)(1) of the Act, we preliminarily find that critical circumstances exist with respect to imports of truck and bus tires from the PRC for mandatory respondent Guizhou Tyre Co., Ltd. (GTC) and its cross-owned trading company, Guizhou Tyre Import and Export Co., Ltd. (GTCIE). A discussion of our determination can be found in the Preliminary Decision Memorandum.

Preliminary Determination and Suspension of Liquidation

In accordance with section 703(d)(1)(A)(i) of the Act, we calculated a CVD rate for each individually-investigated producer/exporter of the subject merchandise. We preliminarily determine that countervailable subsidies are being provided with respect to the manufacture, production, or exportation of the subject merchandise. In accordance with sections 703(d) and 705(c)(5)(A) of the Act, for companies not individually examined, we apply an "all-others" rate, which is normally calculated by weighting the subsidy rates of the individual companies as respondents by those companies' exports of the subject merchandise to the United States. Under section 705(c)(5)(A)(i) of the Act, the all-others rate should exclude zero and *de minimis* rates or any rates based entirely on facts otherwise available pursuant to section 776 of the Act. Neither of the mandatory respondents' rates in this preliminary determination were zero or *de minimis* or based entirely on facts otherwise available. In order to ensure that business proprietary information is not disclosed, we have calculated the all-others rate as a simple average of the countervailable subsidy rates found for the two mandatory repsondents.[6]

We preliminarily determine the countervailable subsidy rates to be:

Company	Subsidy rate (percent)
Double Coin Holdings Ltd.; Double Coin Group (Jiangsu) Tyre Co., Ltd.; Double Coin Group (Chongqing) Tyre Co., Ltd.; Double Coin Group Shanghai Donghai Tyre Co. Ltd.; Double Coin Group (Xinjiang) Kunlun Tyre Co., Ltd.	17.06
Guizhou Tyre Import and Export Co., Ltd.; Guizhou Tyre Co., Ltd.	23.38
All-Others	20.22

In accordance with sections 703(d)(1)(B) and (2) of the Act, we are directing U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of truck and bus tires from the PRC that are entered, or withdrawn from warehouse, for consumption on or after the date of the publication of this notice in the **Federal Register**, and to require a cash deposit for such entries of merchandise in the amounts indicated above. Section 703(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of: (a) The date which is 90 days before the date on which the suspension of liquidation was first ordered; or (b) the date on which notice of initiation of the investigation was published. We preliminarily found that critical circumstances exist for GTC and GTCIE. Therefore, in accordance with section 703(e)(2)(A) of the Act, we are directing CBP to apply the suspension of liquidation to any unliquidated entries entered, or withdrawn form warehouse for consumption by GTC and GTCIE, on or after the date that is 90 days prioir to the publication of this notice in the **Federal Register**.

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[3] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, regarding "Decision Memorandum for the Preliminary Affirmative Determination: Countervailing Duty Investigation of Truck and Bus Tires from the People's Republic of China; and the Preliminary Affirmative Determination of Critical Circummstances, in Part" dated concurrently with this notice (Preliminary Decision Memorandum).

[4] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[5] *See* section 776(a) of the Act.

[6] *See* Preliminary Decision Memorandum at "CALCULATION OF THE ALL-OTHERS RATE" (for further explanation of the business propretiary information concerns).

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted by the respondents prior to making our final determination.

U.S. International Trade Commission

In accordance with section 703(f) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

Disclosure and Public Comment

The Department intends to disclose calculations performed for this preliminary determination to the parties within five days of the date of public announcement of this determination in accordance with 19 CFR 351.224(b). Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in this proceeding, and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[7] A table of contents, list of authorities used, and an executive summary of issues should accompany any briefs submitted to the Department, pursuant to 19 CFR 351.309(c)(2) and (d)(2). This summary should be limited to five pages total, including footnotes.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically-filed request must be received successfully, and in its entirety, by ACCESS by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number; the number of participants; and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a date, time, and specific location to be determined. Parties will be notified of the date, time, and location of any hearing. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: June 27, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of the investigation covers truck and bus tires. Truck and bus tires are new pneumatic tires, of rubber, with a truck or bus size designation. Truck and bus tires covered by this investigation may be tube-type, tubeless, radial, or non-radial.

Subject tires have, at the time of importation, the symbol "DOT" on the sidewall, certifying that the tire conforms to applicable motor vehicle safety standards. Subject tires may also have one of the following suffixes in their tire size designation, which also appear on the sidewall of the tire:

TR—Identifies tires for service on trucks or buses to differentiate them from similarly sized passenger car and light truck tires;

MH—Identifies tires for mobile homes; and

HC—Identifies a 17.5 inch rim diameter code for use on low platform trailers.

All tires with a "TR," "MH," or "HC" suffix in their size designations are covered by this investigation regardless of their intended use.

In addition, all tires that lack one of the above suffix markings are included in the scope, regardless of their intended use, as long as the tire is of a size that is among the numerical size designations listed in the "Truck-Bus" section of the Tire and Rim Association Year Book, as updated annually, unless the tire falls within one of the specific exclusions set out below.

Truck and bus tires, whether or not mounted on wheels or rims, are included in the scope. However, if a subject tire is imported mounted on a wheel or rim, only the tire is covered by the scope. Subject merchandise includes truck and bus tires produced in the subject country whether mounted on wheels or rims in the subject country or in a third country. Truck and bus tires are covered whether or not they are accompanied by other parts, *e.g.*, a wheel, rim, axle parts, bolts, nuts, etc. Truck and bus tires that enter attached to a vehicle are not covered by the scope.

Specifically excluded from the scope of this investigation are the following types of tires: (1) Pneumatic tires, of rubber, that are not new, including recycled and retreaded tires; and (2) non-pneumatic tires, such as solid rubber tires.

The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.20.1015 and 4011.20.5020. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.99.4520, 4011.99.4590, 4011.99.8520, 4011.99.8590, 8708.70.4530, 8708.70.6030, and 8708.70.6060. While HTSUS subheadings are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope Comments
IV. Scope of the Investigation
V. Critical Circumstances
VI. Injury Test
VII. Use of Facts Otherwise Available and Application of Adverse Inferences
VIII. Application of the Countervailing Duty Law to Imports From the PRC
IX. Subsidies Valuation
X. Interest Rate Benchmarks, Discount Rates, Input and Land Benchmarks
XI. Analysis of Programs
XII. Calculation of All-Others Rate
XIII. ITC Notification
XIV. Disclosure and Public Comment
XV. Verification
XVI. Conclusion

[FR Doc. 2016–15837 Filed 7–1–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–039]

Countervailing Duty Investigation of Certain Amorphous Silica Fabric From the People's Republic of China: Preliminary Determination and Alignment of Final Determination With Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain amorphous silica fabric (silica fabric) from the People's Republic of China (the PRC). The period of investigation is January 1, 2015 through December 31,

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[7] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

2015. We invite interested parties to comment on this preliminary determination.

DATES: Effective July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Emily Maloof or John Corrigan, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–5649 or (202) 482–7438, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Investigation

The merchandise covered by this investigation is silica fabric from the PRC. For a complete description of the scope of this investigation, *see* Appendix II.

Scope Comments

In accordance with the preamble to the Department's regulations,[1] we set aside a period of time in our Initiation Notice for parties to raise issues regarding product coverage, and we encouraged all parties to submit comments within 20 calendar days of the signature date of that notice.[2]

We received several comments concerning the scope of the antidumping (AD) and countervailing duty (CVD) investigations of silica fabric from the PRC. We intend to issue our preliminary decision regarding the scope of the AD and CVD investigations in the preliminary determination of the companion AD investigation, which is due for signature on August 24, 2016. On March 13, 2016, Lewco Specialty Products, Inc. (Lewco) submitted a letter that was later rejected by the Department as it was improperly filed.[3] We intend to issue our preliminary decision regarding the scope of the AD and CVD investigations in the preliminary determination of the companion AD investigation, which is due for signature on August 24, 2016.

Methodology

The Department is conducting this CVD investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.*, a financial contribution by an "authority" that gives rise to a benefit to the recipient, and that the subsidy is specific.[4] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.[5] The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov*, and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://trade.gov/enforcement*. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

The Department notes that, in making this preliminary determination, we relied, in part, on facts available and, because one or more respondents did not act to the best of their ability to respond to the Department's requests for information, we drew an adverse inference where appropriate in selecting from among the facts otherwise available.[6] For further information, *see* "Use of Facts Otherwise Available and Adverse Inferences" in the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), we are aligning the final CVD determination in this investigation with the final determination in the companion AD investigation of silica fabric from the PRC based on a request made by Petitioner.[7] Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than November 7, 2016, unless postponed.

Preliminary Determination and Suspension of Liquidation

In accordance with section 703(d)(1)(A)(i) of the Act, we calculated an individual rate for each exporter/producer of the subject merchandise individually investigated. We preliminarily determine the countervailable subsidy rates to be:

Exporter/producer	Subsidy rate (percent)
ACIT (Pinghu) Inc. and ACIT (Shanghai) Inc	4.36
Nanjing Tianyuan Fiberglass Material Co. Ltd	28.25
Acmetex Co., Ltd.,* Beijing Great Pack Materials, Co. Ltd.,* Beijing Landingji Engineering Tech Co., Ltd.,* Changshu Yaoxing Fiberglass Insulation Products Co., Ltd.,* Changzhou Kingze Composite Materials Co., Ltd.,* Changzhou Utek Composite Co.,* Chengdu Chang Yuan Shun Co., Ltd.,* China Beihai Fiberglass Co., Ltd.,* China Yangzhou Guo Tai Fiberglass Co., Ltd.,* Chongqing Polycomp International Corp.,* Chongqing Yangkai Import & Export Trade Co., Ltd.,* Cixi Sunrise Sealing Material Co., Ltd.,*.	

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[1] *See* Antidumping Duties; Countervailing Duties; Final Rule, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*).

[2] *See Certain Amorphous Silica Fabric From the People's Republic of China: Initiation of Countervailing Duty Investigation*, 81 FR 8909 (February 23, 2016) (*Initiation Notice*).

[3] *See* Memorandum to the File from John K. Drury, "Request to Take Action on Certain Barcodes," dated March 18, 2016.

[4] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[5] See Memorandum to Paul Piquado, "Decision Memorandum for the Preliminary Affirmative Determination: Countervailing Duty Investigation of Certain Amorphous Silica Fabric from the People's Republic of China," dated June 27, 2016 (Preliminary Decision Memorandum).

[6] *See* sections 776(a) and (b) of the Act.

[7] Auburn Manufacturing, Inc. (AMI) (Petitioner); *see also* Letter from AMI, "Re: Certain Amorphous Silica Fabric from the People's Republic of China: Petitioner's Request for Postponement of Date for Final Countervailing Duty Determinations to Align to the Date of the Final Antidumping Determination," dated June 9, 2016.

Exporter/producer	Subsidy rate (percent)
Fujian Minshan Fire-Fighting Co., Ltd.,* Grand Fiberglass Co., Ltd.,* Haining Jiete Fiberglass Fabric Co., Ltd.,* Hebei Yuniu Fiberglass Manufacturing Co., Ltd.,* Hebei Yuyin Trade Co., Ltd.,* Hengshui Aohong International Trading Co., Ltd.,* Hitex Insulation (Ningbo) Co., Ltd.,* Mowco Industry Limited,* Nanjing Debeili New Materials Co., Ltd.,* Ningbo Fitow High Strength Composites Co., Ltd.,* Ningbo Universal Star Industry & Trade Limited,* Ningguo BST Thermal Protection Products Co., Ltd.,* Qingdao Feelongda Industry & Trade Co., Ltd.,* Qingdao Shishuo Industry Co., Ltd.,* Rugao City Ouhua Composite Material Co., Ltd.,* Rugao Nebola Fiberglass Co., Ltd.,* Shanghai Bonthe Insulative Material Co., Ltd.,* Shanghai Horse Construction Co., Ltd.,* Shanghai Liankun Electronics Material Co., Ltd.,* Shanghai Suita Environmental Protection Technology Co., Ltd.,* Shangqui Huanyu Fiberglass Co., Ltd.,* Shengzhou Top-Tech New Material Co., Ltd.,* Shenzhen Songxin Silicone Products Co., Ltd.,* Taixing Chuanda Plastic Co., Ltd.,* Taixing Vichen Composite Material Co., Ltd.,* TaiZhou Xinxing Fiberglass Products Co., Ltd.,* Tenglong Sealing Products Manufactory Yuyao,* Texaspro (China) Company,* Wallean Industries Co., Ltd.,* Wuxi First Special-Type Fiberglass Co., Ltd.,* Wuxi Xingxiao Hi-Tech Material Co., Ltd.,* Yuyao Feida Insulation Sealing Factory,* Yuyao Tianyi Special Carbon Fiber Co., Ltd.,* Zibo Irvine Trading Co., Ltd.,* Zibo Yao Xing Fire-Resistant and Heat-Preservation Material Co., Ltd.,* Zibo Yuntai Furnace Technology Co., Ltd.*	104.10
All-Others	4.36

*Non-cooperative company to which an adverse facts available rate is being applied. *See* "Use of Facts Otherwise Available and Adverse Inferences," section in the Preliminary Decision Memorandum.

In accordance with sections 703(d)(1)(B) and (d)(2) of the Act, we are directing U.S. Customs and Border Protection to suspend liquidation of all entries of silica fabric from the PRC that are entered, or withdrawn from warehouse, for consumption on or after the date of the publication of this notice in the **Federal Register**, and to require a cash deposit for such entries of merchandise in the amounts indicated above.

Sections 703(d) and 705(c)(5)(A) of the Act state that, for companies not investigated, we determine an "all-others rate," by weighting the subsidy rates of the individual company subsidy rate of each of the companies investigated by each company's exports of subject merchandise to the United States excluding rates that are zero or *de minimis* or any rates determined entirely on the facts available. Notwithstanding the language of section 705(c)(5)(A)(i) of the Act, we have not calculated the "all-others" rate by weight-averaging the rates of the two individually investigated respondents, because the rate calculated for Nanjing Tianyuan was determined entirely on facts available. Therefore, for the "all-others" rate, we applied the rate calculated for ACIT Pinghu.

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted by the respondents prior to making our final determination.

Disclosure and Public Comment

The Department will disclose calculations performed for this preliminary determination to the parties within five days of the date of public announcement of this determination in accordance with 19 CFR 351.224(b). Case briefs or other written comments for all non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in this proceeding, and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[8] A table of contents, list of authorities used and an executive summary of issues should accompany any briefs submitted to the Department. This summary should be limited to five pages total, including footnotes.

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically filed request for a hearing must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice.[9] Requests should contain the party's name, address, and telephone number; the number of participants; and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230, at a date and time to be determined. Parties will be notified of the date and time of any hearing. The hearing will be limited to issues raised in the respective briefs.[10]

International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission (ITC) of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: June 27, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
  A. Initiation and Case History
  B. Postponement of Preliminary Determination
  C. Period of Investigation
III. Alignment
IV. Scope Comments
V. Scope of the Investigation
VI. Injury Test
VII. Application of the CVD Law to Imports From the PRC
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[8] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[9] *See* 19 CFR 351.310(c).

[10] *Id.*

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Appendix II

Scope of the Investigation

The product covered by this investigation is woven (whether from yarns or rovings) industrial grade amorphous silica fabric, which contains a minimum of 90 percent silica (SiO_2) by nominal weight, and a nominal width in excess of 8 inches. The investigation covers industrial grade amorphous silica fabric regardless of other materials contained in the fabric, regardless of whether in roll form or cut-to-length, regardless of weight, width (except as noted above), or length. The investigation covers industrial grade amorphous silica fabric regardless of whether the product is approved by a standards testing body (such as being Factory Mutual (FM) Approved), or regardless of whether it meets any governmental specification.

Industrial grade amorphous silica fabric may be produced in various colors. The investigation covers industrial grade amorphous silica fabric regardless of whether the fabric is colored. Industrial grade amorphous silica fabric may be coated or treated with materials that include, but are not limited to, oils, vermiculite, acrylic latex compound, silicone, aluminized polyester (Mylar®) film, pressure-sensitive adhesive, or other coatings and treatments. The investigation covers industrial grade amorphous silica fabric regardless of whether the fabric is coated or treated, and regardless of coating or treatment weight as a percentage of total product weight. Industrial grade amorphous silica fabric may be heat-cleaned. The investigation covers industrial grade amorphous silica fabric regardless of whether the fabric is heat-cleaned.

Industrial grade amorphous silica fabric may be imported in rolls or may be cut-to-length and then further fabricated to make welding curtains, welding blankets, welding pads, fire blankets, fire pads, or fire screens. Regardless of the name, all industrial grade amorphous silica fabric that has been further cut-to-length or cut-to-width or further finished by finishing the edges and/or adding grommets, is included within the scope of this investigation.

Subject merchandise also includes (1) any industrial grade amorphous silica fabric that has been converted into industrial grade amorphous silica fabric in China from fiberglass cloth produced in a third country; and (2) any industrial grade amorphous silica fabric that has been further processed in a third country prior to export to the United States, including but not limited to treating, coating, slitting, cutting to length, cutting to width, finishing the edges, adding grommets, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope industrial grade amorphous silica fabric.

Excluded from the scope of the investigation is amorphous silica fabric that is subjected to controlled shrinkage, which is also called "pre-shrunk" or "aerospace grade" amorphous silica fabric. In order to be excluded as a pre-shrunk or aerospace grade amorphous silica fabric, the amorphous silica fabric must meet the following exclusion criteria: (1) The amorphous silica fabric must contain a minimum of 98 percent silica (SiO_2) by nominal weight; (2) the amorphous silica fabric must have an areal shrinkage of 4 percent or less; (3) the amorphous silica fabric must contain no coatings or treatments; and (4) the amorphous silica fabric must be white in color. For purposes of this scope, "areal shrinkage" refers to the extent to which a specimen of amorphous silica fabric shrinks while subjected to heating at 1800 degrees F for 30 minutes.

Areal shrinkage is expressed as the following percentage:

$$\frac{\text{Fired Area, cm}^2 - \text{Initial Area, cm}^2}{\text{Initial Area, cm}^2} \times 100 = \text{Areal Shrinkage, \%}$$

Also excluded from the scope are amorphous silica fabric rope and tubing (or sleeving). Amorphous silica fabric rope is a knitted or braided product made from amorphous silica yarns. Silica tubing (or sleeving) is braided into a hollow sleeve from amorphous silica yarns.

The subject imports are normally classified in subheadings 7019.59.4021, 7019.59.4096, 7019.59.9021, and 7019.59.9096 of the Harmonized Tariff Schedule of the United States (HTSUS), but may also enter under HTSUS subheadings 7019.40.4030, 7019.40.4060, 7019.40.9030, 7019.40.9060, 7019.51.9010, 7019.51.9090, 7019.52.9010, 7019.52.9021, 7019.52.9096 and 7019.90.1000. HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of this investigation is dispositive.

[FR Doc. 2016–15729 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results of Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On May 26, 2016, the Department of Commerce (the "Department") published its notice of initiation and preliminary results of a changed circumstances review of the

antidumping duty ("AD") order on crystalline silicon photovoltaic cells, whether or not assembled into modules ("solar cells"), from the People's Republic of China ("PRC").[1] The Department preliminarily determined that Hangzhou Sunny Energy Science and Technology Co., Ltd. ("Hangzhou Sunny") is the successor-in-interest to Hangzhou Zhejiang University Sunny Energy Science and Technology Co., Ltd. ("Hangzhou ZU Sunny") for purposes of the AD order on solar cells from the PRC and, as such, is entitled to Hangzhou ZU Sunny's cash deposit rate with respect to entries of subject merchandise. We invited interested parties to comment on the *Preliminary Results.* As no parties submitted comments, and there is no other information or evidence on the record calling into question our *Preliminary Results,* the Department is making no changes to the *Preliminary Results.* For these final results, the Department continues to find that Hangzhou Sunny is the successor in interest to Hangzhou ZU Sunny.

DATES: *Effective Date:* July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2769.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012, the Department published the AD Order on solar cells from the PRC in the **Federal Register**.[2] On April 4, 2016, Hangzhou Sunny requested that the Department initiate an expedited changed circumstances review to determine that Hangzhou Sunny is the successor-in-interest to Hangzhou ZU Sunny for AD purposes.[3] On May 20, 2016, the Department initiated a changed circumstances review and made a preliminary finding that Hangzhou Sunny is the successor-in-interest to Hangzhou ZU Sunny, and is entitled to Hangzhou ZU Sunny's cash deposit rate with respect to entries of merchandise subject to the AD Order on solar cells from the PRC.[4] We provided interested parties 14 days from the date of publication of the *Preliminary Results* to submit case briefs. No interested parties submitted case briefs or requested a hearing.

Scope of the Order

The merchandise covered by the Order is crystalline silicon photovoltaic cells, whether or not assembled into modules, subject to certain exceptions.[5] Merchandise covered by this Order is currently classified in the Harmonized Tariff System of the United States ("HTSUS") under subheadings 8501.61.0000, 8507.20.80, 8541.40.6020, 8541.40.6030, and 8501.31.8000. While these HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of this Order is dispositive.

Final Results of Changed Circumstances Review

Because the record contains no information or evidence that calls into question the *Preliminary Results,* for the reasons stated in the *Preliminary Results,* the Department continues to find that Hangzhou Sunny is the successor-in-interest to Hangzhou ZU Sunny, and is entitled to Hangzhou ZU Sunny's cash deposit rate with respect to entries of merchandise subject to the AD Order on solar cells from the PRC.[6] We are issuing this determination and publishing these final results and notice in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Tariff Act of 1930, as amended ("the Act"), and 19 CFR 351.216 and 351.221(c)(3).

Instructions to U.S. Customs and Border Protection

Based on these final results, we will instruct U.S. Customs and Border Protection to collect estimated antidumping duties for all shipments of subject merchandise exported by Hangzhou Sunny and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at the current AD cash deposit rate for Hangzhou ZU Sunny (*i.e.,* 9.67 percent).[7] This cash deposit requirement shall remain in effect until further notice.

Notification to Interested Parties

This notice serves as a final reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

We are issuing and publishing this final results notice in accordance with sections 751(b) and 777(i) of the Act and 19 CFR 351.216.

Dated: June 28, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–15836 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

Background

Every five years, pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"), the Department of Commerce ("the Department") and the International Trade Commission automatically initiate and conduct a review to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

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[1] *See Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules From the People's Republic of China,* 81 FR 33463 (May 26, 2016) ("*Preliminary Results*"), and accompanying Preliminary Decision Memorandum.

[2] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012) ("Order").

[3] *See* Letter from Hangzhou Sunny to the Department regarding, "Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from the People's Republic of China: Request for Expedited Changed Circumstances Review" (April 4, 2016) ("CCR Request").

[4] *See Preliminary Results,* 81 FR 33463.

[5] For a complete description of the scope of the Order, *see* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Preliminary Results of Changed Circumstances Review: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China" ("Preliminary Results Memorandum").

[6] For a complete discussion of the Department's findings, which remain unchanged in these final results and which are herein incorporated by reference and adopted by this notice, *see generally* the Preliminary Results Memorandum accompanying the *Preliminary Results.*

[7] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2012–2013,* 80 FR 40998 (June 14, 2015).

Upcoming Sunset Reviews for August 2016

The following Sunset Reviews are scheduled for initiation in August 2016 and will appear in that month's Notice of Initiation of Five-Year Sunset Review ("Sunset Review").

	Department contact
Antidumping Duty Proceedings	
Glycine from China (A–570–836) (4th Review)	Jacqueline Arrowsmith, (202) 482–5255.
Polyester Staple Fiber from the Republic of Korea (A–580–839) (3rd Review)	David Goldberger, (202) 482–4136.
Polyester Staple Fiber from Taiwan (A–583–833) (3rd Review)	David Goldberger, (202) 482–4136.

Countervailing Duty Proceedings

No Sunset Review of countervailing duty orders is scheduled for initiation in August 2016.

Suspended Investigations

No Sunset Review of suspended investigations is scheduled for initiation in August 2016.

The Department's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. The Notice of Initiation of Five-Year ("Sunset") Reviews provides further information regarding what is required of all parties to participate in Sunset Reviews.

Pursuant to 19 CFR 351.103(c), the Department will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact the Department in writing within 10 days of the publication of the Notice of Initiation.

Please note that if the Department receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue. Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: June 28, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–15724 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Waters, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended ("the Act"), may request, in accordance with 19 CFR 351.213, that the Department of Commerce ("the Department") conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by the Department discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, the Department intends to select respondents based on U.S. Customs and Border Protection ("CBP") data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order ("APO") to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. The Department invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event the Department decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, the Department finds that determinations concerning whether particular companies should be "collapsed" (*i.e.*, treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.*, investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that the Department may extend this time if it is reasonable to do so. In order to provide parties additional certainty with respect to when the Department will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after July 2016, the Department does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance prevented it from submitting a timely withdrawal request. Determinations by the Department to extend the 90-day deadline will be made on a case-by-case basis.

The Department is providing this notice on its Web site, as well as in its "Opportunity to Request Administrative Review" notices, so that interested parties will be aware of the manner in which the Department intends to exercise its discretion in the future.

Opportunity To Request A Review: Not later than the last day of July 2016,[1] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in July for the following periods:

	Period of Review
Antidumping Duty Proceedings	
INDIA: Polyethylene Terephthalate (Pet) Film, A–533–824	7/1/15–6/30/16
IRAN: In-Shell Pistachios, A–507–502	7/1/15–6/30/16
ITALY: Certain Pasta, A–475–818	7/1/15–6/30/16
JAPAN:	
Clad Steel Plate, A–588–838	7/1/15–6/30/16
Polyvinyl Alcohol, A–588–861	7/1/15–6/30/16
Stainless Steel Sheet and Strip in Coils, A–588–845	7/1/15–6/30/16
MALAYSIA:	
Steel Nails, A–557–816	12/29/14–6/30/16
Welded Stainless Steel Pressure Pipe, A–557–815	7/1/15–6/30/16
OMAN: Steel Nails, A–523–808	12/29/14–6/30/16
REPUBLIC OF KOREA:	
Stainless Steel Sheet and Strip in Coils, A–580–834	7/1/15–6/30/16
Steel Nails, A–580–874	12/29/14–6/30/16
RUSSIA: Solid Urea, A–821–801	7/1/15–6/30/16
SOCIALIST REPUBLIC OF VIETNAM:	
Steel Nails, A–552–818	12/29/14–6/30/16
Welded Stainless Steel Pressure Pipe, A–552–816	7/1/15–6/30/16
TAIWAN:	
Polyethylene Terephthalate (Pet) Film, A–583–837	7/1/15–6/30/16
Stainless Steel Sheet and Strip in Coils, A–583–831	7/1/15–6/30/16
Steel Nails, A–583–854	5/20/15–6/30/16
THAILAND:	
Carbon Steel Butt-Weld Pipe Fittings, A–549–807	7/1/15–6/30/16
Welded Stainless Steel Pressure Pipe, A–549–830	7/1/15–6/30/16
THE PEOPLE'S REPUBLIC OF CHINA:	
Carbon Steel Butt-Weld Pipe Fittings, A–570–814	7/1/15–6/30/16
Certain Potassium Phosphate Salts, A–570–962	7/1/15–6/30/16
Certain Steel Grating, A–570–947	7/1/15–6/30/16
Circular Welded Carbon Quality Steel Pipe, A–570–910	7/1/15–6/30/16
Persulfates, A–570–847	7/1/15–6/30/16
Xanthan Gum, A–570–985	7/1/15–6/30/16
TURKEY: Certain Pasta, A–489–805	7/1/15–6/30/16
UKRAINE: Solid Urea, A–823–801	7/1/15–6/30/16
Countervailing Duty Proceedings	
INDIA: Polyethylene Terephthalate (Pet) Film, C–533–825	1/1/15–12/31/15
ITALY: Certain Pasta, C–475–819	1/1/15–12/31/15
SOCIALIST REPUBLIC OF VIETNAM: Steel Nails, C–552–819	11/3/14–12/31/15
THE PEOPLE'S REPUBLIC OF CHINA:	
Circular Welded Carbon Quality Steel Pipe, C–570–911	1/1/15–12/31/15
Potassium Phosphate Salts, C–570–963	1/1/15–12/31/15
Prestressed Concrete Steel Wire Strand, C–570–946	1/1/15–12/31/15
Steel Grating, C–570–948	1/1/15–12/31/15
TURKEY: Certain Pasta, C–489–806	1/1/15–12/31/15

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[1] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when the Department is closed.

	Period of Review
Suspension Agreements	
UKRAINE: Oil Country Tubular Goods, A–823–815	7/1/15–6/30/16

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party the Department was unable to locate in prior segments, the Department will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011) the Department clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[2]

Further, as explained in *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963 (November 4, 2013), the Department clarified its practice with regard to the conditional review of the non-market economy (NME) entity in administrative reviews of antidumping duty orders. The Department will no longer consider the NME entity as an exporter conditionally subject to administrative reviews. Accordingly, the NME entity will not be under review unless the Department specifically receives a request for, or self-initiates, a review of the NME entity.[3] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, the Department will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, the Department will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System ("ACCESS") on Enforcement and Compliance's ACCESS Web site at *http://access.trade.gov*.[4] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

The Department will publish in the **Federal Register** a notice of "Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation" for requests received by the last day of July 2016. If the Department does not receive, by the last day of July 2016, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures "gap" period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: June 28, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–15726 Filed 7–1–16; 8:45 am]

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[2] *See also* the Enforcement and Compliance Web site at *http://trade.gov/enforcement/*.

[3] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[4] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–828]

Stainless Steel Butt-Weld Pipe Fittings From Italy: Final Results of Antidumping Duty Administrative Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On February 26, 2016, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on stainless steel butt-weld pipe fittings from Italy.[1] The review covers one producer/exporter of the subject merchandise, Filmag Italia S.p.A. (Filmag). The period of review is from February 1, 2014, through January 31, 2015. As a result of our analysis of comments received, the final results differ from the preliminary results of review. For the final, weighted-average dumping margin, *see* the "Final Results of Review" section below.

DATES: *Effective Date:* July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Edythe Artman or Brian Davis, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–7924 or (202) 482–3931, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 26, 2016, the Department published the *Preliminary Results.* In accordance with 19 CFR 351.309(c)(1)(ii), we invited parties to comment on these results. We received comments from Filmag on March 25, 2016, but received no comments from any domestic interested parties.

Scope of the Order

For purposes of the order, the product covered is certain stainless steel butt-weld pipe fittings. Stainless steel butt-weld pipe fittings are under 14 inches in outside diameter (based on nominal pipe size), whether finished or unfinished. The product encompasses all grades of stainless steel and "commodity" and "specialty" fittings. Specifically excluded from the definition are threaded, grooved, and bolted fittings, and fittings made from any material other than stainless steel.

The butt-weld fittings subject to the order is currently classifiable under subheading 7307.23.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order is dispositive.[2]

Analysis of Comments Received

The issues raised by Filmag in its case brief are addressed in the Issues and Decision Memorandum. A list of these issues is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on-file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users on the Internet at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on a review of the record and one of Filmag's comments, we made changes to its margin calculations for the final results of review. Specifically, we revised the gross unit price for Filmag's reported U.S. sales to include movement expenses incurred on its sales and which are deducted as part of the adjustments we make to calculate export price.

Final Results of Review

As a result of this review, the Department determines the weighted-average dumping margin for the period February 1, 2014, through January 31, 2015, is as follows:

Manufacturer/exporter	Weighted-average margin (percent)
Filmag Italia S.p.A	17.29

Disclosure

We will disclose the calculation memorandum used in our analysis to interested parties within five days of the date of the publication of these final results pursuant to 19 CFR 351.224(b).

Duty Assessment

The Department shall determine and U.S. Customs and Border Protection (CBP) shall assess antidumping duties on all appropriate entries.[3] Because Filmag's weighted-average dumping margin is above *de minimis,* we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). Upon issuance of the final results of this administrative review, if any importer-specific assessment rates calculated in the final results are above *de minimis* (*i.e.,* at or above 0.5 percent), the Department will issue instructions directly to CBP to assess antidumping duties on appropriate entries.

To determine whether the duty assessment rate covering the period was *de minimis* for Filmag, in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated an importer-specific, *ad valorem* rate by aggregating the amount of dumping calculated for all U.S. sales to that importer and dividing this amount by the total entered value of the sales to that importer. Where an importer-specific *ad valorem* rate is greater than *de minimis,* and the respondent has reported reliable entered values, we apply the assessment rate to the entered value of the importer's entries during the review period.

We intend to issue assessment instructions directly to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of this notice for all shipments of subject merchandise

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[1] *See Stainless Steel Butt-Weld Pipe Fittings From Italy: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015,* 81 FR 9806 (February 26, 2016) (*Preliminary Results*).

[2] For a full description of the scope of the order, *see* the Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, on the subject of "Issues and Decision Memorandum for Final Results of Antidumping Duty Administrative Review: Stainless Steel Butt-Weld Pipe Fittings from Italy; 2014–2015" (Issues and Decision Memorandum), which is issued concurrently with, and hereby adopted by, this notice.

[3] In these final results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

entered, or withdrawn from warehouse, for consumption on or after the publication of these final results, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for the respondent noted above will be the rate established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the manufacturer of the subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 26.59 percent, the all-others rate established in the antidumping investigation.[4] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the period of review. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: June 27, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Final Issues and Decision Memorandum

I. Summary
II. List of Issues
III. Background
IV. Scope of the Order
V. Discussion of Interested Party Comments
  Comment 1: The Calculation of Normal Value Based on Sales of Similar Products
  Comment 2: The Calculation of Export Price Based on U.S. Gross Unit Price
VI. Recommendation

[FR Doc. 2016–15835 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Open Meeting of the Commission on Enhancing National Cybersecurity

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The Commission on Enhancing National Cybersecurity will meet Thursday, July 14, 2016, from 9:00 a.m. until 5:00 p.m. Central Time at the Hilton University of Houston. The primary purpose of the meeting is to discuss the challenges and opportunities facing cybersecurity for critical infrastructure, as well as State and local governments and cybersecurity. In particular, the meeting will address: (1) Current and future effects of critical infrastructure on the digital economy; (2) critical infrastructure cybersecurity challenges affecting the digital economy; and (3) cybersecurity challenges and opportunities in State and local governments. The meeting will support detailed recommendations to strengthen cybersecurity in both the public and private sectors while protecting privacy, ensuring public safety and economic and national security, fostering discovery and development of new technical solutions, and bolstering partnerships between Federal, State, local, tribal and territorial governments and the private sector in the development, promotion, and use of cybersecurity technologies, policies, and best practices. All sessions will be open to the public.

DATES: The meeting will be held on Thursday, July 14, 2016, from 9:00 a.m. until 5:00 p.m. Central Time.

ADDRESSES: The meeting will be held at the Hilton University of Houston, in the Conrad Room, 2nd Floor, located at 4450 University Drive, Houston, Texas 77004. The meeting is open to the public and interested parties are requested to contact Sara Kerman at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice in advance of the meeting for building entrance requirements.

FOR FURTHER INFORMATION CONTACT: Sara Kerman, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2000, Gaithersburg, MD 20899–8900, telephone: 301–975–4634, or by email at: *eo-commission@nist.gov.* Please use subject line "*Open Meeting of the Commission on Enhancing National Cybersecurity—TX*".

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Commission on Enhancing National Cybersecurity ("the Commission") will meet Thursday, July 14, 2016, from 9:00 a.m. until 5:00 p.m. Central Time. All sessions will be open to the public. The Commission is authorized by Executive Order 13718, Commission on Enhancing National Cybersecurity.[1] The Commission was established by the President and will make detailed recommendations to strengthen cybersecurity in both the public and private sectors while protecting privacy, ensuring public safety and economic and national security, fostering discovery and development of new technical solutions, and bolstering partnerships between Federal, state, local, tribal and territorial governments and the private sector in the development, promotion, and use of cybersecurity technologies, policies, and best practices.

The agenda is expected to include the following items:

—Introductions
—Panel discussion on current and future effects of critical infrastructure on the digital economy
—Panel discussion on critical infrastructure cybersecurity challenges affecting the digital economy
—Panel discussion on cybersecurity challenges and opportunities in State and local governments

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[4] *See Antidumping Duty Orders: Stainless Steel Butt-Weld Pipe Fittings From Italy, Malaysia, and the Philippines,* 66 FR 11257, 11258 (February, 23, 2001).

[1] *https://www.federalregister.gov/articles/2016/02/12/2016-03038/commission-on-enhancing-national-cybersecurity.*

—Conclusion

Note that agenda items may change without notice. The final agenda will be posted on *http://www.nist.gov/cybercommission.* Seating will be available for the public and media. No registration is required to attend this meeting; however, on-site attendees are asked to voluntarily sign in and space will be available on a first-come, first-served basis.

Public Participation: The Commission agenda will include a period of time, not to exceed fifteen minutes, for oral comments from the public on Thursday, July 14, 2016, from 3:00 p.m. until 3:15 p.m. Central Time. Speakers will be selected on a first-come, first-served basis. Each speaker will be limited to five minutes. Questions from the public will not be considered during this period. Members of the public who are interested in speaking are requested to contact Sara Kerman at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements. In addition, written statements are invited and may be submitted to the Commission at any time. All written statements should be directed to the Commission Executive Director, Information Technology Laboratory, 100 Bureau Drive, Stop 8900, National Institute of Standards and Technology, Gaithersburg, MD 20899–8900 or by email at: *cybercommission@nist.gov.* Please use subject line "*Open Meeting of the Commission on Enhancing National Cybersecurity*—TX"..

Pursuant to 41 CFR 102–3.150(b), this **Federal Register** notice for this meeting is being published fewer than 15 calendar days prior to the meeting as exceptional circumstances exist. It is imperative that the meeting be held on July 14, 2016 to accommodate the scheduling priorities of the key participants, who must maintain a strict schedule of meetings in order to complete the Commission's report by December 1, 2016, as required by Executive Order 13718 § 3(e) (February 9, 2016). Notice of the meeting is also posted on the National Institute of Standards and Technology's Web site at *http://www.nist.gov/cybercommission.*

Kevin Kimball,

Chief of Staff.

[FR Doc. 2016–15790 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE711

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold a webinar-based meeting with its for-hire advisory panel members and the public to gather input regarding an upcoming Council Omnibus Framework action that could require electronic reporting of for-hire Vessel Trip Reports (VTRs) starting January 1, 2017 for all Council-managed fisheries that require for-hire VTR reporting.

DATES: The meeting will be held Monday, July 18, 2016 from 6 p.m.–8 p.m.

ADDRESSES: The meeting will be held via webinar (*http://mafmc.adobeconnect.com/evtr/*) with a telephone audio connection (provided when connecting).

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's Web site, *www.mafmc.org* also has details on the proposed agenda, webinar access, and briefing materials.

SUPPLEMENTARY INFORMATION: The Council is considering electronic reporting of for-hire Vessel Trip Reports (VTRs) starting January 1, 2017. This action would change the method of transmitting VTRs—the required data elements would not change. VTRs would be required to be completed before arriving at the dock, and electronic reports would have to be submitted within 24 hours after docking. This meeting will gather input from the Council's for-hire advisory panel members and the public in preparation for Council action at the August 2016 meeting in Virginia Beach, VA (*http://www.mafmc.org/meetings/*).

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: June 28, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–15768 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE400

Endangered Species; File Nos. 17304, 18238, 18926, 19496, 19528, 19621, 19637, and 19716

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that seven permits and one permit modification have been issued permits to take green (*Chelonia mydas*), hawksbill (*Eretmochelys imbricata*), Kemp's ridley (*Lepidochelys kempii*), leatherback (*Dermochelys coriacea*), loggerhead (*Caretta caretta*) and/or olive ridley (*Lepidochelys olivacea*) sea turtles for purposes of scientific research. See **SUPPLEMENTARY INFORMATION** for additional information regarding permittees.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Arturo Herrera or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** that a request for a scientific research permit to take sea turtles had been submitted by the below-named individuals or organizations as follows:

- *File No. 17304–02:* October 5, 2015 (80 FR 60129)
- *File No. 18238:* July 29, 2015 (80 FR 45203)
- *File Nos. 18926 and 19528:* September 14, 2015 (80 FR 55095)
- *File No. 19496:* January 13, 2016 (81 FR 1621)
- *File No. 19621:* October 5, 2015 (80 FR 60123)

- *File No. 19637:* January 19, 2016 (81 FR 2846)
- *File No. 19716:* January 6, 2016 (81 FR 462)

The requested permits have been issued under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226). The following summarizes each permit.

Permit No. 17304 issued to Dr. Kristen Hart [U.S. Geological Survey, 3205 College Ave., Davie, FL 33314] authorizes researchers to capture green, loggerhead, Kemp's ridley, and hawksbill sea turtles annually by hand or net in the northern Gulf of Mexico. Alternative to direct capture, researchers may obtain sea turtles for study that are legally captured during relocation trawling for the U.S. Army Corps of Engineers. Researchers may examine, biologically sample, tag, and measure sea turtles before release and temporarily track satellite tagged animals after release. Dr. Hart has been issued a permit modification (Permit No. 17304–02) to (1) add trawling as a capture method, and (2) increase the number of Kemp's ridley and loggerhead sea turtles that may be taken annually. The permit expires on September 30, 2018.

The NMFS Southwest Fisheries Science Center (SWFSC), [File No. 18238; 8901 La Jolla Shore Dr., La Jolla, CA 92037, (Responsible Party: Lisa Ballance, Ph.D.)] has been issued a five-year permit to conduct research on green, loggerhead, olive ridley sea turtles in southern California waters. Researchers may conduct vessel surveys for counts, captures, examination, observation, marking, biological sampling, tagging, and morphometrics.

Jane Provancha [File No. 18926; Mail Code: IHA–005 OHF, Room 1104, Kennedy Space Center, FL 32815] has been issued a five-year permit to continue monitoring the abundance and distribution of sea turtles inhabiting the waters of the northern Indian River Lagoon and Mosquito Lagoon system, Florida. Researchers may capture by hand, tangle, or dip net green, Kemp's ridley, hawksbill, and loggerhead sea turtles for morphometric measures, tagging, and/or biological sampling before release.

Dr. Mariana Fuentes [File No. 19496; Florida State University, 581 Oakland Avenue, Tallahassee, FL 32301] has been issued a five-year permit to conduct year-round field activities in the Florida Big Bend Region to take 1,225 sea turtles annually during vessel surveys for count and capture up to 480 sea turtles by hand, dip net or strike net. The following procedures will be performed before release: Measure; weigh; blood, scute, and biopsy sampling; temporary carapace marking; tag; satellite tagging; and/or photography/videography.

Michael Bresette [File No. 19528; Inwater Research Group Inc., 4160 NE. Hyline Dr., Jensen Beach, FL 34957] has been issued a five-year permit to study sea turtles in waters of the Indian River and Miami-Dade Counties in southeastern Florida. Researchers may count and identify green, loggerhead, hawksbill, Kemp's ridley, and leatherback sea turtles during vessel surveys and capture animals by hand or net. Captured animals may be examined, measured, tagged, marked, photographed, and biologically sampled before release.

Dr. Michael Arendt [Permit No. 19621; South Carolina Department of Natural Resources, Marine Resources Division, 217 Fort Johnson Road, Charleston, SC 29412] has been issued a five-year permit to study green, Kemp's ridley, leatherback, and loggerhead sea turtles in the waters of Florida, Georgia and South Carolina. Researchers may capture animals by trawl or tangle net and perform the following procedures before release: Morphometrics, tagging, photography, biological sampling, ultrasound, marking, laparoscopy and associated transport, and/or epibiota removal. A limited number of sea turtles may accidentally die due to capture over the life of the permit.

Dr. Allen Foley [File No. 19637; Florida Fish and Wildlife Conservation Commission, Fish and Wildlife Research Institute, 370 Zoo Parkway, Jacksonville, FL 32218] has been issued a five-year permit to conduct research within the boundaries of the Everglades NP in the vicinity of Arsnicker, Rabbit, and Twin Keys. The research will be from May to August and the applicant will approach and count up to 100 green sea turtles annually during vessel surveys and capture up to 125 loggerheads, 10 Kemp's ridleys, and 5 hawksbills. Sea turtles will be captured by hand and the following procedures will be performed before release: Measure, photograph, weigh, tag, temporary carapace marking, and blood sample. Up to 10 loggerheads also would have tumors tissue sampled annually.

Dr. Robert Hardy [File No. 19716; 100 8th Avenue Southeast Florida Fish and Wildlife Conservation Commission, Fish & Wildlife Research Institute, St. Petersburg, FL 33701] has been issued a five-year permit to conduct research in the surface-pelagic drift communities of the Atlantic Ocean and Gulf of Mexico. The applicant will conduct vessel capture by dip net up to 300 loggerhead, 200 green, 60 hawksbill, 130 Kemp's ridley and 10 leatherback sea turtles annually. Additionally, 150 loggerheads and 440 leatherbacks would be counted during vessel surveys but not for capture. Depending on life stage and size, sea turtles would have the following procedures performed prior to release: Measure, weigh, oral swab, esophageal lavage, skin and scute biopsy, tag, and/or epoxy attachment of a satellite or VHF transmitter. Voided fecal samples also would be collected opportunistically.

Issuance of the permits, as required by the ESA, was based on a finding that each permit (1) was applied for in good faith, (2) will not operate to the disadvantage of such endangered or threatened species, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: June 28, 2016.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–15776 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE713

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (MAFMC's) Summer Flounder, Scup, and Black Sea Bass Monitoring Committee (MC) will hold a public meeting.

DATES: The meeting will be held on Monday, July 25, 2016, from 1 p.m. to 5 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar with a telephone-only connection option. Details on webinar registration and telephone-only connection details will be available at: *http://www.mafmc.org*.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State

Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their Web site at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Summer Flounder, Scup, and Black Sea Bass Monitoring Committee will meet from 1 p.m. to 5 p.m. to review and discuss previously implemented 2017 commercial and recreational Annual Catch Limits (ACLs) and Annual Catch Targets (ACTs) for these three species. The Monitoring Committee may consider recommending changes to the implemented 2017 ACLs and ACTs and other management measures as necessary. Meeting materials will be posted to *http://www.mafmc.org/* prior to the meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders at the Mid-Atlantic Council Office, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: June 29, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–15809 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE712

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Ecosystem and Ocean Planning Committee (EOP) of the Mid-Atlantic Fishery Management Council (Council) will hold a meeting.

DATES: The meeting will be held on Thursday and Friday, July 21–22, 2016, beginning at 1:30 p.m. on July 21 and conclude by 2 p.m. on July 22. For agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will at the Royal Sonesta Harbor Court, 550 Light Street, Baltimore, MD 21202; telephone: (410) 234–0550.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their Web site at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of the meeting to discuss and approve the Council's Ecosystem Approach to Fisheries Management Guidance Document which will be presented to the Council at its August 2016 meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders at the Mid-Atlantic Council Office, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: June 29, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–15808 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE615

Marine Mammals; File No. 20324

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that a permit has been issued to Living Planet Productions/Silverback Films, 1 St Augustines Yard, Gaunts Lane, Bristol, BS1 5DE, United Kingdom [Responsible Party: Emily Lascelles], to conduct commercial or educational photography on bottlenose dolphins (*Tursiops truncatus*).

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On May 13, 2016, notice was published in the **Federal Register** (81 FR 29846) that a request for a permit to conduct commercial or educational photography on bottlenose dolphins in the Florida Bay had been submitted by the above-named applicant. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The permit authorizes filming and photography of the Florida Bay stock of bottlenose dolphins for purposes of a documentary film. Dolphins may be harassed during aerial and vessel-based filming activities. Filming may take place for approximately 30 days over two field seasons. The permit is valid through July 31, 2017.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: June 28, 2016.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–15775 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2016–0013]

Elimination of Publication Requirement in the Collaborative Search Pilot Program Between the Japan Patent Office and the United States Patent and Trademark Office

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) implemented a Collaborative Search Pilot Program with the Japan Patent Office (JPO) on August 1, 2015, to study whether the exchange of search results between offices for corresponding counterpart applications improves patent quality and facilitates the examination of patent applications in both offices. Based upon feedback from the public, the USPTO is modifying the Collaborative Search Pilot Program between JPO and USPTO (JPO–CSP) by removing the requirement that the applications must be published in order to participate in the pilot program. The JPO and USPTO have determined that publication of the applications is unnecessary for participation in the pilot program and that unpublished applications can participate in the pilot program as long as applicants grant access to the unpublished application and provide a translated copy of the currently pending claims from the corresponding counterpart application(s). Accordingly, publication of an application will no longer be a prerequisite for participation in the JPO–CSP as of the effective date of this notice. Instead, if unpublished, applicant must provide an authorization of access to the unpublished application and submit a translation of the currently pending claims from the corresponding counterpart application(s). These modifications should permit more applications to qualify for the program, supporting the program's study of the efficacy of exchanging search results between corresponding counterpart applications to improve patent quality and facilitate examination.

DATES: *Effective Date:* August 1, 2016.

Duration: Under this pilot program, the USPTO and JPO will continue to accept petitions to participate until August 1, 2017, two years from the original effective date of the program (August 1, 2015). During each year, the pilot program will be limited to 400 granted petitions, 200 granted petitions where USPTO performs the first search and JPO performs the second search, and 200 granted petitions where JPO performs the first search and USPTO performs the second search. The offices may extend the pilot program (with or without modification) for an additional amount of time, if necessary. The offices reserve the right to terminate the pilot program at any time.

FOR FURTHER INFORMATION CONTACT: Daniel Hunter, Director of International Work Sharing, Planning and Implementation, Office of International Patent Cooperation by telephone at (571) 272–8050 regarding the handling of any specific application participating in the pilot. Any questions concerning this notice may be directed to Joseph Weiss, Senior Legal Advisor, Office of Patent Legal Administration by telephone at (571) 272–7759. Any inquiries regarding this pilot program can be emailed to *wspilots@uspto.gov.*

SUPPLEMENTARY INFORMATION: The USPTO published a notice to implement a joint work sharing initiative, a Collaborative Search Pilot Program, between JPO and USPTO on July 10, 2015. *See United States Patent and Trademark Office and Japan Patent Office Collaborative Search Pilot Program,* 80 FR 39752 (July 10, 2015), 1417 *Off. Gaz. Pat. Office* 68 (August 4, 2015) (*JPO–CSP* Notice). The *JPO–CSP* Notice indicated that an applicant can request, via petition to make special, to have an application advanced out of turn (accorded special status) for examination, if the application was published and satisfied other requirements specified in the *JPO–CSP* Notice. The pilot program is designed to ensure the applications are contemporaneously examined so that examiners from both offices have a more comprehensive set of references along with corresponding claim sets before them when making initial patentability determinations. The USPTO has received feedback and suggestions from stakeholders regarding the pilot program's design.

Under the JPO–CSP as originally implemented, each office conducted a prior art search for its corresponding counterpart application and then exchanged the search results with the other office before either office issued a communication to the applicant regarding patentability. As a result of this exchange of search results, the examiners in both offices had a more comprehensive set of references before them when making their initial patentability determinations. As only published applications were permitted, examiners also had access to the currently pending claims of both applications.

The USPTO and JPO have determined that the publication requirement in the *JPO–CSP* Notice is unnecessary as long as the petition authorizes access to the unpublished application and includes a translation of the currently pending claims from the corresponding counterpart application(s). Accordingly, the USPTO is modifying the JPO–CSP to remove the publication requirement and instead require the applicant to authorize access to the application and at least a machine translation of the currently pending claims from the corresponding counterpart application(s).

To participate in the pilot program, applicants should now use Form PTO/SB/437JP–U, which is available at *http://www.uspto.gov/patent/patents-forms,* when filing a petition to make special under this pilot program satisfying all other requirements set forth in the *JPO–CSP* Notice. Requirements (1)–(3) set forth in Part III of the original *JPO–CSP* Notice of August 1, 2015, are modified by this notice to reflect the modifications discussed above. They are now as follows:

(1) The application must be a non-reissue, non-provisional utility application filed under 35 U.S.C. 111(a), or an international application that has entered the national stage in compliance with 35 U.S.C. 371(c) with an effective filing date no earlier than March 16, 2013. The U.S. application and the corresponding JPO counterpart application must have a common earliest priority date that is no earlier than March 16, 2013.

(2) A completed petition form PTO/SB/437JP–U must be filed in the application via EFS-web. Form PTO/SB/437JP–U is available at *http://www.uspto.gov/patent/patents-forms.* If the application is unpublished the petition must include a translated copy of the currently pending claims from the corresponding counterpart application(s). A machine translation is acceptable.

(3) The petition submission must include an express written consent under 35 U.S.C. 122(c) for the USPTO to receive prior art references and comments from the JPO that will be considered during the examination of the U.S. application participating in this JPO Work Sharing Pilot Program. The petition also must provide written authorization for the USPTO to provide JPO access to the participating U.S. application's bibliographic data and search reports in accordance with 35 U.S.C. 122(a) and 37 CFR 1.14(c). Form PTO/SB/437JP–U includes language compliant with the consent requirement(s) for this pilot program.

All other requirements and provisions set forth in the *JPO–CSP* Notice remain unchanged. Please see the *JPO–CSP* Notice for more information on the program.

Dated: June 28, 2016.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2016–15850 Filed 7–1–16; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD16–16–000]

Implementation Issues Under the Public Utility Regulatory Policies Act of 1978; Supplemental Notice of Technical Conference

As announced in the Notice of Technical Conference issued in this proceeding on February 9, 2016, the Federal Energy Regulatory Commission (Commission) will hold a technical conference on June 29, 2016, from 9:00 a.m. to approximately 4:00 p.m. on implementation issues under the Public Utility Regulatory Policies Act of 1978 (PURPA).[1] The conference will be held in the Commission Meeting Room at the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The purpose of the technical conference is to focus on issues associated with the Commission's implementation of PURPA. As noted in the preliminary agenda previously issued in this proceeding,[2] the conference will focus on two issues: The mandatory purchase obligation under PURPA and the determination of avoided costs for those purchases.

A final Agenda for the technical conference, including speakers, is attached.

Those who plan to attend the technical conference are strongly encouraged to complete the registration form located at: *https://www.ferc.gov/whats-new/registration/06-29-16-form.asp.* There is no registration deadline or fee to attend the conference.

Information on this event will be posted on the Calendar of Events on the Commission's Web site, *http://www.ferc.gov,* prior to the event. The conference will be transcribed. Transcripts will be available for a fee from Ace Reporting Company (202–347–3700). A free webcast of this event is also available through *www.ferc.gov.* Anyone with Internet access who desires to view this event can do so by navigating to *http://www.ferc.gov* Calendar of Events and locating this event in the Calendar. The event will contain a link to the webcast. The Capitol Connection provides technical support for webcasts and offers the option of listening to the meeting via phone-bridge for a fee. If you have any questions, visit *www.CapitolConnection.org* or call 703–993–3100.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or (202) 208–1659 (TTY), or send a FAX to (202) 208–2106 with the required accommodations.

While this conference is not for the purpose of discussing specific cases, we note that the discussions at the conference may address matters at issue in the following Commission proceedings that are either pending or within their rehearing period:

	Docket Nos.
Occidental Chemical Corporation	EL13–41–001
Tri-State Generation and Transmission Association, Inc.	EL16–39–000
Bright Light Capital, LLC	EL16–43–000, QF16–259–001
Nebraska Public Power District	QM16–1–000
Ameren Illinois Company and Union Electric Company	QM16–2–000
Gregory and Beverly Swecker v. Midland Power Cooperative	EL14–9–000, QF11–424–002
Gregory and Beverly Swecker v. Midland Power Cooperative and Central Iowa Power Cooperative.	EL14–18–000
Interconnect Solar Development LLC	EL16–55–000, QF11–204–002, QF11–205–002
SunE B9 Holdings, LLC	EL16–58–000, QF15–793–001, QF15–794–001, QF15–795–001
Golden Spread Electric Cooperative, Inc.	QM16–3–000
Golden Spread Electric Cooperative, Inc.	EL16–62–000
Oklahoma Municipal Power Authority	EL16–67–000
Saguaro Power Company	EL16–78–000, QF90–203–007
North Hartland, LLC	EL16–74–000, QF99–56–004
Graphic Packaging International, Inc.	ER16–1051–000, ER16–1051–001
Hoosier Energy Rural Electric Cooperative Inc.	QM16–4–000
Windham Solar LLC and Allco Finance Limited	EL16–69–000, QF16–362–001, QF16–363–001, QF16–364–001, QF16–365–001, QF16–366–001, QF16–367–001, QF16–368–001, QF16–369–001, QF16–370–001, QF16–371–001, QF16–372–001, QF16–373–001, QF16–374–001, QF16–375–001, QF16–376–001, QF16–377–001, QF16–378–001, QF16–379–001, QF16–380–001, QF16–381–001, QF16–382–001, QF16–383–001, QF16–384–001, QF16–385–001, QF16–386–001, QF16–387–001

For more information about the technical conference, please contact:

Technical Information: Adam Alvarez, Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6734, *Adam.Alvarez@ferc.gov.*

Legal Information: Loni Silva, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6233, *Loni.Silva@ferc.gov.*

Logistical Information: Sarah McKinley, Office of External Affairs, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8368, *Sarah.Mckinley@ferc.gov.*

Dated: June 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–15792 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

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[1] 16 U.S.C. 824a–3 (2012).

[2] Supplemental Notice Concerning Technical Conference, 81 FR 12,726 (2016).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File date	Presenter or requester
Prohibited:		
1. CP16–21–000	6–13–2016	Carolyn Thomas.
2. ER14–1485–000	6–16–2016	Perry J. Mitchell.
3. CP16–21–000	6–22–2016	Gina Schowald.
4. CP16–116–000	6–22–2016	Felipe Saenz.
Exempt:		
1. CP16–9–000	6–13–2016	U.S. Senators.[1]
2. CP15–554–000	6–17–2016	U.S. House Representative Chris Van Hollen.
3. CP15–18–001	6–20–2016	U.S Congress.[2]
4. P–1904–073, P–1892–024, P–1855–045	6–22–2016	U.S. Senator Kelly A. Ayotte.
5. ER16–307–000	6–22–2016	U.S. Congress.[3]
6. CP15–558–000	6–22–2016	State of New Jersey Assemblyman Jack M. Ciattarelli.
7. CP16–116–000	6–22–2016	State of Texas Senator Eddie Lucio, Jr.
8. CP16–116–000	6–22–2016	Port Isabel Chamber of Commerce.

[1] Senators Elizabeth Warren and Edward J. Markey.

[2] Senators Thomas R. Carper and Christopher A. Coons. House Representative John C. Carney, Jr.

[3] Senators Sheldon Whitehouse and Jack Reed. House Representatives James R. Langevin and David N. Cicilline.

Dated: June 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–15795 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–92–000]

New York State Public Service Commission, New York Power Authority, Long Island Power Authority, New York State Energy Research & Development Authority, City of New York, Advanced Energy Management Alliance, Natural Resources Defense Council, v. New York Independent System Operator, Inc.

Notice of Complaint

Take notice that on June 24, 2016, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824e and 825e (2012) and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, New York State Public Service Commission, New York Power Authority, Long Island Power Authority, New York State Energy Research & Development Authority, City of New York, Advanced Energy Management Alliance and Natural Resources Defense Council (collectively the Complainants) filed a formal complaint against New York Independent System Operator, Inc. (NYISO or Respondent) alleging the application of the NYISO's buyer-side market (BSM) power mitigation measures contained in section 23.4 of attachment H of the NYISO's Market Administration and Control Area Services Tariff results in BSM rules that limit full Special Case Resources participation, interfere with Federal, State and local policy objectives, and are therefore unjust and unreasonable, as more fully explained in the complaint.

Complainants certifies that copies of the complaint were served on the contacts for Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on July 14, 2016.

Dated: June 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15778 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–93–000]

NextEra Energy Resources, LLC PSEG Companies v. ISO New England Inc.; Notice of Complaint

Take notice that on June 24, 2016, pursuant to section 206 of the Federal Power Act, 16 U.S.C. 824e and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, NextEra Energy Resources, LLC and PSEG Companies (Complainants) filed a formal complaint against ISO New England Inc. (Respondent) seeking revision of the ISO New England Inc.'s Transmission, Markets and Services Tariff. Complainants assert that such revisions will ensure that prices in ISO New England energy and capacity markets will remain just and reasonable, as more fully explained in the complaint.

Complainants certifies that copies of the complaint were served on the contacts for Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on July 14, 2016.

Dated: June 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–15794 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–134–000.
Applicants: Chaves County Solar, LLC, Live Oak Solar, LLC, Marshall Solar, LLC, River Bend Solar, LLC.
Description: Application for Authorization Under FPA Section 203 and Request for Expedited Action of Chaves County Solar, LLC, et al.
Filed Date: 6/24/16.
Accession Number: 20160624–5256.
Comments Due: 5 p.m. ET 7/15/16.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–123–000.
Applicants: Victoria WLE, LP.
Description: Notice of Change in Facts Regarding Exempt Wholesale Generator Status of Victoria WLE, LP.
Filed Date: 6/24/16.
Accession Number: 20160624–5153.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: EG16–124–000.
Applicants: Five Points Solar Park LLC.
Description: Notice of Self-Certification of Exempt Wholesale GeneratorStatus of Five Points Solar Park LLC.
Filed Date: 6/24/16.
Accession Number: 20160624–5222.
Comments Due: 5 p.m. ET 7/15/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–2019–000.
Applicants: Five Points Solar Park LLC.
Description: Baseline eTariff Filing: Five Points Solar Park LLC MBR Filing to be effective 6/25/2016.
Filed Date: 6/24/16.
Accession Number: 20160624–5187.
Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2020–000.

Applicants: NRG Potomac River LLC.

Description: Tariff Cancellation: Notice of Cancellation to be effective 6/25/2016.

Filed Date: 6/24/16.

Accession Number: 20160624–5189.

Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2021–000.

Applicants: FirstLight Hydro Generating Company.

Description: § 205(d) Rate Filing: FirstLight Change in Status to be effective 6/25/2016 .

Filed Date: 6/24/16.

Accession Number: 20160624–5190.

Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2022–000.

Applicants: FirstLight Power Resources Management, LLC.

Description: § 205(d) Rate Filing: FirstLight Change in Status to be effective 6/25/2016.

Filed Date: 6/24/16.

Accession Number: 20160624–5191.

Comments Due: 5 p.m. ET 7/15/16.

Docket Numbers: ER16–2023–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 20160624 Flexible Ramping Product to be effective 10/1/2016.

Filed Date: 6/24/16.

Accession Number: 20160624–5194.

Comments Due: 5 p.m. ET 7/15/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15777 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Schedule for Environmental Review of the Mountain Valley Pipeine Project and the Equitrans Expansion Project

	Docket No.
Mountain Valley Pipeline LLC.	CP16–10–000
Equitrans LP	CP16–13–000

On October 23, 2015, Mountain Valley Pipeline LLC (Mountain Valley) filed its application with the Federal Energy Regulatory Commission (FERC or Commission) in Docket No. CP16–10–000, requesting a Certificate of Public Convenience and Necessity pursuant to Section 7(c) of the Natural Gas Act to construct, operate, and maintain certain natural gas pipeline facilities. Equitrans LP (Equitrans) filed a companion application on October 27, 2015 in Docket No. CP16–13–000. The proposed Mountain Valley Pipeline Project, in West Virginia and Virginia, would transport about 2 billion cubic feet per day (Bcf/d) of natural gas from production areas in the Appalachian Basin to markets on the East Coast. The proposed Equitrans Expansion Project, in Pennsylvania and West Virginia, would transport about 0.4 Bcf/d of natural gas and interconnect with the Mountain Valley Pipeline. Because these are interrelated projects, the FERC staff deemed it was appropriate to analyze them in a single environmental impact statement (EIS).

On November 5, 2015, the FERC issued its Notice of Application for the projects. Among other things, that notice alerted other agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on the request for a federal authorization within 90 days of the date of issuance of the Commission staff's final EIS for the projects. This instant notice identifies the FERC staff's planned schedule for completion of the final EIS for the projects, which is based on an issuance of the draft EIS in September 2016.

Schedule for Environmental Review

Issuance of Notice of Availability of the final EIS, March 10, 2017

90-day Federal Authorization Decision Deadline, June 8, 2017

If a schedule change becomes necessary for the final EIS, an additional notice will be provided so that the relevant agencies are kept informed of the projects' progress.

Project Description

The Mountain Valley Pipeline Project would consist of about 301 miles of new 42-inch-diameter pipeline, beginning at the Mobley Interconnect and receipt meter station in Wetzel County, West Virginia, and terminating at the Transco Interconnect and delivery meter station at the existing Transcontinental Gas Pipe Line Company Compressor Station 165 in Pittsylvania County, Virginia. In addition, Mountain Valley intends to construct and operate three new compressor stations and other aboveground facilities.

The Equitrans Expansion Project would consist of a total of about 8 miles of various diameter pipelines in six segments. These segments include the parallel 12-inch-diameter H–158 pipeline and 6-inch-diameter M–80 pipeline extending about 0.2-mile each in Greene County, Pennsylvania; the 24-inch-diameter H–305 pipeline that would extend about 540 feet in Greene County; the 3-mile-long new 30-inch-diameter H–316 pipeline in Greene County; the 4.2-mile-long new 20-inch-diameter H–318 pipeline in Allegheny and Washington Counties, Pennsylvania; and the new H–319 pipeline that would extend about 200 feet in Wetzel County, West Virginia. Equitrans also proposes to abandon its existing Pratt Compressor Station and replace it with the new Redhook Compressor Station in Greene County, Pennsylvania; and to construct and operate taps in Greene County and Washington County, Pennsylvania, and an interconnect and two taps in Wetzel County, West Virginia,

Background

On October 31, 2014 and April 9, 2015, the Commission staff granted Mountain Valley's and Equitrans' requests to use the FERC's pre-filing environmental review process and assigned the Mountain Valley Pipeline Project temporary Docket No. PF15–3–000 and the Equitrans Expansion Project temporary Docket No. PF15–22–000. The FERC issued a *Notice of Intent to Prepare and Environmental Impact Statement for the Planned Mountain Valley Pipeline Project, Request for Comments on Environmental Issues, and Notice of Public Scoping Meetings* (NOI) on April 17, 2015. An NOI for the Equitrans Expansion Project was issued on August 11, 2015, with a scoping period for that project that ended on September 14, 2015.

The NOIs were issued during the pre-filing review of the projects, and were sent to our environmental mailing list that included federal, state, and local government agencies; elected officials; affected landowners; regional environmental groups and non-governmental organizations; Native Americans and Indian tribes; local libraries and newspapers; and other interested parties. The Mountain Valley Pipeline Project NOI announced the date, time, and location of six public meetings sponsored by the FERC in the project area, and a scoping period that ran to June 16, 2015 to take comments on the project. Some of the major issues raised during scoping included potential impacts on karst terrain and caves; impacts on groundwater and springs, drinking water supplies, and surface waterbodies; impacts on forest; impacts on property values and the use of eminent domain; impacts on tourism; impacts on public recreational areas such as the Jefferson National Forest, Appalachian National Scenic Trail, and the Blue Ridge Parkway; impacts on historic districts; and pipeline safety.

The United States (U.S.) Department of Agriculture Forest Service, Jefferson National Forest; U.S. Army Corps of Engineers, Huntington and Norfolk Districts; U.S. Department of the Interior, Bureau of Land Management; U.S. Environmental Protection Agency, Region 3; Pipeline and Hazardous Materials Safety Administration within the U.S. Department of Transportation; West Virginia Department of Environmental Protection; and West Virginia Division of Natural Resources are cooperating agencies in the preparation of the EIS.

Additional Information

In order to receive notification of the issuance of the EIS and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription (*http://www.ferc.gov/docs-filing/esubscription.asp*). Additional data about the projects can be obtained electronically through the Commission's Internet Web site (*www.ferc.gov*). Under "Dockets & Filings," use the "eLibrary" link, select "General Search" from the menu, enter the docket numbers excluding the last three digits (*i.e.,* CP16–10 or CP16–13), and the search dates. Questions about the projects can be directed to the Commission's Office of External Affairs at (866) 208–FERC.

Dated: June 28, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–15796 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1947–000]

Atlantic Energy MD, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Atlantic Energy MD, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 18, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15781 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1946–000]

Atlantic Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Atlantic Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 18, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15780 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1913–000]

River Bend Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of River Bend Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 18, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15779 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–468–000]

Pine Prairie Energy Center, LLC; Notice of Request Under Blanket Authorization

Take notice that on June 15, 2016, Pine Prairie Energy Center, LLC (Pine Prairie), 333 Clay Street, Suite 1500, Houston, Texas 77002, filed in Docket No. CP16–468–000, a prior notice request pursuant to sections 157.205, 157.208, and 157.213 of the Commission's regulations under the Natural Gas Act (NGA). Pine Prairie seeks authorization to construct two additional electric motor drive compressors within the gas handling facility located at the Pine Prairie Energy Center in Evangeline Parish, Louisiana. Pine Prairie states this installation will have no effect on the certificated working gas storage capacity nor its certificated maximum daily deliverability or injection capability of the facility. Pine Prairie proposes to perform these activities under its blanket certificate issued in Docket No. CP04–381–000, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may be viewed on the Web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to James F. Bowe, Jr., King & Spalding LLP, 1700 Pennsylvania Avenue NW., Suite 200, Washington, DC 20006–4707, or by calling (202) 626–9601 (telephone) or (202) 626–3737 (fax), *jbowe@kslaw.com,* or to Eileen Wilson Kisluk, Pine Prairie Energy Center, LLC, 333 Clay Street, Suite 1500, Houston, Texas 77002, or by calling (713) 993–5203 (telephone) or (713) 652–3701 (fax), *ewkisluk@pnglp.com.*

Any person or the Commission's Staff may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to Section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper. See 18 CFR 385.2001(a) (1) (iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the "e-Filing" link. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: June 27, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–15793 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1948–000]

Atlantic Energy MA LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Atlantic Energy MA LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 18, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 27, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–15782 Filed 7–1–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9948–69–OA]

Notification of a Partially Closed Meeting of the Science Advisory Board's 2016–2018 Scientific and Technological Achievement Awards Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency's (EPA), Science Advisory Board (SAB) Staff Office is announcing a meeting of the SAB's 2016–2018 Scientific and Technological Achievement Awards (STAA) Committee to discuss draft recommendations for the chartered SAB regarding the Agency's 2016 STAA recipients. A portion of the meeting will be closed to the public.

DATES: The meeting dates are Monday, August 15, 2016, from 8:00 a.m. to 6:00 p.m. (Eastern Time), and Tuesday, August 16, 2016, from 8:00 a.m. to 3:00 p.m. (Eastern Time). The public portion of the meeting will be held on Monday, August 15, 2016, from 1:00 p.m. to 4:00 p.m. (Eastern Time). The remainder of the meeting will be closed to the public.

ADDRESSES: The meeting will be held at the Melrose Georgetown Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain further information regarding the meeting of the 2016–2018 Staff Committee may contact Edward Hanlon, Designated Federal Officer, by telephone: (202) 564–2134 or email at *hanlon.edward@epa.gov.* The SAB Mailing address is EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460. General information about the SAB as well as updates concerning the SAB meeting announced in this notice may be found on the SAB Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background: Pursuant to section 10(d) of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, and section (c)(6) of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6), the EPA has determined that a portion of the 2016–2018 STAA Committee meeting will be closed to the public. The purpose of the closed portion of the meeting is for the Committee to discuss draft recommendations regarding recipients of the Agency's 2016 Scientific and Technological Achievement Awards. The purpose of the open portion of the meeting, which will occur on Monday, August 15, 2016, from 1:00 p.m. to 4:00 p.m. (Eastern Time), is to discuss administrative changes to the STAA nomination procedures, and the criteria for deciding which STAA nominations merit award.

The STAA awards are established to honor and recognize EPA employees who have made outstanding contributions in the advancement of science and technology through their research and development activities, as exhibited in publication of their results in peer reviewed journals. I have determined that a portion of the 2016–2018 STAA Committee meeting will be closed to the public because it is concerned with recommending employees deserving of awards. In making these draft recommendations, the SAB requires full and frank advice from the Committee. This advice will involve professional judgments on the relative merits of various employees and their respective work. Such personnel matters involve the discussion of information that is of a personal nature and the disclosure of which would be a clearly unwarranted invasion of personal privacy and, therefore, are protected from disclosure by section (c)(6) of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6). Minutes of the 2016–2018 STAA Committee meeting will be kept and certified by the chair.

Availability of Meeting Materials: Prior to the public portion of the meeting, the agenda and other materials will be accessible through the meeting link on the SAB home page at *http://www.epa.gov/sab/*.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Interested members of the public may submit relevant information on the topic of the public portion of this advisory activity, and/or the group conducting the activity, for the SAB to consider during the advisory process. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for SAB committees and panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly.

Oral Statements: In general, individuals or groups requesting an oral presentation at an SAB public meeting will be limited to five minutes. Interested parties wishing to provide comments at the public portion of the August 15, 2016 meeting should contact Mr. Hanlon, DFO, in writing (preferably via email) at the contact information noted above by August 8, 2016, to be placed on the list of public speakers for the meeting.

Written Statements: Written statements will be accepted throughout the advisory process; however, for timely consideration by Committee members, statements should be supplied to Mr. Hanlon, DFO (preferably via email) at the contact information noted above by August 8, 2016. It is the SAB Staff Office general policy to post written comments on the Web page for advisory meetings. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Hanlon at the contact information provided above. To request accommodation of a disability, please contact Mr. Hanlon preferably at least ten days prior to the meeting to give EPA as much time as possible to process your request.

Dated: June 27, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2016–15856 Filed 7–1–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9948–70–OA]

Meetings of the Local Government Advisory Committee and the Small Communities Advisory Subcommittee

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Small Communities Advisory Subcommittee (SCAS) will meet in Washington, DC, on Thursday, July 28, 2016, 8:00 a.m.–9:30 a.m. (EDT). The Subcommittee will discuss drinking water; rural strategy; and other issues and recommendations to the Administrator regarding environmental issues affecting small communities. The Local Government Advisory Committee (LGAC) will meet Washington, DC, on Wednesday, July 27, 2016, 1:00 p.m.–5:00 p.m. (EDT); Thursday, July 28, 2016, 9:30 p.m.–5:30 p.m.; and Friday, July 29, 2016, 8:30 a.m.–12:30 p.m. (EDT). The focus of the Committee meeting will be on issues pertaining to protecting America's waters; hydraulic fracturing; drinking water; Plan EJ 2020; cleaning up our communities; air, climate and energy; and climate change resiliency and sustainability.

These are open meetings, and all interested persons are invited to participate. The SCAS will hear comments from the public between 9:00 a.m. and 9:10 a.m. on Thursday, July 28, 2016, and the LGAC will hear comments from the public between 2:30 p.m. and 2:45 p.m. on Wednesday, July 27, 2016. Individuals or organizations wishing to address the Committee will be allowed a maximum of five minutes to present their point of view. Also, written comments should be submitted electronically to *eargle.frances@epa.gov*. Please contact the Designated Federal Officer (DFO) at the number listed below to schedule a time on the agenda. To address the subcommittee, please contact *matthews.demond@epa.gov*. Time will be allotted on a first-come first-serve basis, and the total period for comments may be extended if the number of requests for appearances requires it.

ADDRESSES: The Small Communities Advisory Subcommittee meetings will be held at the U.S. Environmental Protection Agency, East Building, Conference Room 1153, 1301 Constitution Ave. NW., Washington, DC 20460. The Local Government Advisory Committee meetings will be held at the U.S. Environmental Protection Agency, Conference Room 1153, 1301 Constitution Ave. NW., Washington, DC 20460. Meeting summaries will be available after the meeting online at *www.epa.gov/ocir/scas_lgac/lgac_index.htm* and can be obtained by written request to the DFO.

FOR FURTHER INFORMATION CONTACT: Local Government Advisory Committee (LGAC) contact Frances Eargle, Designated Federal Officer, at (202) 564–3115 or email at *eargle.frances@epa.gov*. For the Small Communities Advisory Subcommittee (SCAS), contact Demond Matthews, Designated Federal Officer, at (202) 564–3781 or email at *matthews.demond@epa.gov*.

SUPPLEMENTARY INFORMATION:

Information on services for those with disabilities: For information on access or services for individuals with disabilities, please contact Frances Eargle at (202) 564–3115 or email at *eargle.frances@epa.gov*. To request accommodation of a disability, please request it 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: June 21, 2016.

Frances Eargle,

Designated Federal Officer, Local Government Advisory Committee.

[FR Doc. 2016–15854 Filed 7–1–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2015–0744; FRL–9946–87]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 0794.16); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: "Notification of Substantial Risk of Injury to Health and the Environment under TSCA Sec. 8(e)" and identified by EPA ICR No. 0794.16 and OMB Control No. 2070–0046, represents the renewal of an existing ICR that is scheduled to expire on February 28, 2017. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before September 6, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2015–0744, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: David Brooks, Risk Assessment Division (7403T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8603; email address: *brooks.david@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Notification of Substantial Risk of Injury to Health and the Environment under TSCA Sec. 8(e).

ICR number: EPA ICR No. 0794.16.

OMB control number: OMB Control No. 2070–0046.

ICR status: This ICR is currently scheduled to expire on February 28, 2017. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 8(e) of the Toxic Substances Control Act (TSCA) requires that any person who manufactures, imports, processes or distributes in commerce a chemical substance or mixture and which obtains information that reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment must immediately inform EPA of such information. EPA routinely disseminates TSCA section 8(e) data it receives to other federal agencies to provide information about newly discovered chemical hazards and risks. This information collection refers to the reporting requirement described above.

Responses to the collection of information are mandatory (see 15 U.S.C. 2607(e)). Respondents may claim all or part of a notice confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range from 0.5 hours to 50 hours per response, depending upon the nature of the response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are companies that manufacture, process, import or distribute in commerce a chemical substance or mixture, and that obtain information that reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment.

Estimated total number of potential respondents: 65.

Frequency of response: On occasion.

Estimated total average number of responses for each respondent: 8.8.

Estimated total annual burden hours: 21,412 hours.

Estimated total annual costs: $1,650,068. This includes an estimated burden cost of $1,650,068 and an estimated cost of $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is an increase of 2,894 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects EPA's revised estimates of the number of TSCA sec. 8(e) initial submissions. This change is an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: June 22, 2016.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2016–15857 Filed 7–1–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket ID No. EPA–HQ–ORD–2016–0374; FRL–9948–71–ORD]

Evaluating Urban Resilience to Climate Change: A Multi-Sector Approach; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; correction.

SUMMARY: The Environmental Protection Agency (EPA) published a document in the **Federal Register** of June 21, 2016, announcing a 30-day public comment period for the draft document titled "Evaluating Urban Resilience to Climate Change: A Multi-Sector Approach" (EPA/600/R–15/312). The document contained an incorrect docket number.

FOR FURTHER INFORMATION CONTACT: For technical information, contact Susan Julius, NCEA; telephone: 703–347–8619; facsimile: 703–347–8694; or email: *julius.susan@epa.gov.*

Correction

In the **Federal Register** of June 21, 2016, in FR Doc. 2016–14666, on page 40302, in the document heading and on page 40303, in the first column, in the first paragraph of section II. and in the same column, in the "*Instructions:*" paragraph, the docket number is corrected to read: EPA–HQ–ORD–2016–0374.

Dated: June 24, 2016.

Mary A. Ross,

Deputy Director, National Center for Environmental Assessment.

[FR Doc. 2016–15855 Filed 7–1–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[PS Docket No. 15–94; DA 16–721]

Public Safety and Homeland Security Bureau Launches EAS Test Reporting System (ETRS) and Seeks Comment on EAS Operating Handbook Recommendations

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document provides notice to all Emergency Alert System (EAS) Participants that the EAS Test Reporting System (ETRS) is operational and is ready to accept filings. Initial instructions are also provided on how EAS Participants are to begin the ETRS filing process. This document also seeks comment on the recommendations adopted by the Communications Security, Reliability, and Interoperability Council (CSRIC) on June 22, 2016, for updating the EAS Operating Handbook (Handbook). Comments will support future FCC guidance regarding Handbook use.

DATES: Comments are due on or before July 20, 2016.

ADDRESSES: You may submit comments, identified by PS Docket No. 15–94, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *Paper Filers:* Parties that choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th St. SW., Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432. For detailed instructions for submitting comments, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Austin Randazzo, Attorney Advisor, Public Safety and Homeland Security Bureau, at (202) 418–1462, or by email at *Austin.Randazzo@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Public Notice in PS Docket No. 15–94, released on June 27, 2016. The document is available for download at *https://apps.fcc.gov/edocs_public/attachmatch/DA-16-721A1.pdf.* The complete text of the document is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

The proceeding initiated by Part III of the document shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. To the extent any other aspect of the Public Notice involves a proceeding or a presentation under the Commission's ex parte rules, it is exempt from the application of those rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum.

Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.*, .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Federal Communications Commission.

David Furth,

Deputy Chief, Public Safety and Homeland Security Bureau.

[FR Doc. 2016–15849 Filed 6–30–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0572]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before September 6, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0572.

Title: International Circuit Status Reports, 47 CFR 43.82.

Form No.: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Responses and Respondents: 75 respondents and 75 responses.

Estimated Time per Response: 1 hour–50 hours.

Frequency of Response: Annual reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The Commission has authority for this information collection pursuant to the Communications Act of 1934 Sections 4, 48, 48 Stat. 1066, as amended, 47 U.S.C. 154 unless otherwise noted. Interpret or apply Sections 211, 219, 48 Stat. 1073, 1077, as amended; 47 U.S.C. 211, 219 and 220.

Total Annual Burden: 736 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general there is no need for confidentiality with this collection of information.

Needs and Uses: The Federal Communications Commission ("Commission") is requesting a three-year extension of the delegated authority information collection under OMB Control No. 3060–0572 titled, "International Circuit Status Reports, 47 CFR 43.82" from the Office of Management and Budget (OMB).

Section 47 CFR 43.82 of the Commission's rules requires that each common carrier engaged in providing facilities-based international telecommunications services between the United States and foreign points shall file annually the status of its circuits used to provide international services. The annual circuit-status report, required by Section 43.82, provides the Commission, the carriers, and others information on how U.S. international carriers use their circuits. The Commission uses the information from the circuit-status reports to ensure that carriers with market power do not use their access to circuit capacity to engage in any anti-competitive behavior. The Commission also uses the reports to implement the requirement in Section 9 of the Communications Act of 1934, as amended, that carriers pay annual regulatory fees for each of the bearer circuits they own.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–15818 Filed 7–1–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0751]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before September 6, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0751.

Title: Contracts and Concessions, 47 CFR 43.51.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents/Responses: 10 respondents; 40 responses.

Estimated Time per Response: 6–8 hours.

Frequency of Response: Annual reporting requirement; on occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in 47 U.S.C. 154, 211, 219 and 220.

Total Annual Burden: 300 hours.

Annual Cost Burden: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general, there is no need for confidentiality with this collection of information.

Needs and Uses: This collection will be submitted as an extension (no change in reporting or recordkeeping requirements) after this 60-day comment period to the Office of Management and Budget (OMB) in order to obtain the full three year clearance.

The Commission has determined that the authorized resale of international private lines inter-connected to the U.S. public switched network would tend to divert international message telephone service (IMTS) traffic from the settlements process and increase the U.S. net settlements deficit. The information will be used by the Commission in reviewing the impact, if any, that end-user private line interconnections have on the Commission's international settlements policy. The data will also enhance the ability of both the Commission and interested parties to monitor the unauthorized resale of international private lines that are interconnected to the U.S. public switched network.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–15817 Filed 7–1–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee on Community Banking; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463 (Oct. 6, 1972), 5 U.S.C. App. 2, notice is hereby given of a meeting of the FDIC Advisory Committee on Community Banking, which will be held in Washington, DC. The Advisory Committee will provide advice and recommendations on a broad range of policy issues that have particular impact on small community banks throughout the United States and the local communities they serve, with a focus on rural areas.

DATES: Wednesday, July 20, 2016, from 9:00 a.m. to 3:00 p.m.

ADDRESSES: The meeting will be held in the FDIC Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of current issues affecting community banking. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call (703) 562–6067 (Voice or TTY) at least two days before the meeting to make necessary arrangements. Written statements may be filed with the committee before or after the meeting. This Community Banking Advisory Committee meeting will be Webcast live via the Internet at *https://fdic.primetime.mediaplatform.com/#/channel/1384299242770/Advisory+Committee+on+Community+Banking+.* Questions or troubleshooting help can be found at the same link. For optimal viewing, a high speed internet connection is recommended. The Community Banking meeting videos are made available on-demand approximately two weeks after the event.

Federal Deposit Insurance Corporation.

Dated: June 29, 2016.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–15789 Filed 7–1–16; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Proposed Agency Information Collection Activities: Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice and request for comment.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35), the OCC, the Board, and the FDIC (the agencies) may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), have approved the publication for public comment of a proposal to revise and extend the Market Risk Regulatory Report for Institutions Subject to the Market Risk Capital Rule (FFIEC 102), which is currently an approved collection of information for each agency. The agencies propose to modify this collection effective December 31, 2016, to (1) have institutions provide their Legal Entity Identifier (LEI) on the reporting form, only if they already have one, and (2) add U.S. Intermediate Holding Companies (IHCs) to the Board's respondent panel.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the FFIEC and the agencies should modify the proposed revisions prior to giving final approval. The agencies will then submit the revisions to OMB for review and approval.

DATES: Comments must be submitted on or before September 6, 2016.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the OMB control number, will be shared among the agencies.

OCC: Because paper mail in the Washington, DC, area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible, to *prainfo@occ.treas.gov.* Alternatively, comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0325 (FFIEC 102), 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326.

You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comments or supporting materials that you consider confidential or inappropriate for public disclosure.

Board: You may submit comments, which should refer to "FFIEC 102" by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at: *http://www.federalreserve.gov/apps/foia/ProposedRegs.aspx.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include reporting form number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert DeV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/apps/foia/ProposedRegs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 3515, 1801 K Street (between 18th and 19th Streets) NW., Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments, which should refer to "FFIEC 102," by any of the following methods:

- *Agency Web site: http://www.fdic.gov/regulations/laws/federal/.* Follow the instructions for submitting comments on the FDIC Web site.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: comments@FDIC.gov.* Include "FFIEC 102" in the subject line of the message.
- *Mail:* Manuel E. Cabeza, Counsel, Room MB–3105, Attn: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Public Inspection: All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal/* including any personal information provided. Paper copies of public comments may be requested from the FDIC Public Information Center by telephone at (877) 275–3342 or (703) 562–2200.

Additionally, commenters may send a copy of their comments to the OMB desk officer for the agencies by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503; by fax to (202) 395–6974; or by email to *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about the proposed revisions to the FFIEC 102 discussed in this notice, please contact any of the agency clearance officers whose names appear below. In addition, copies of the FFIEC 102 reporting form and instructions are available on the FFIEC's Web site (*http://www.ffiec.gov/ffiec_report_forms.htm*).

OCC: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, or for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

Board: Nuha Elmaghrabi, Federal Reserve Board Clearance Officer, (202) 452–3884, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Manuel E. Cabeza, Counsel, (202) 898–3767, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION: The agencies are proposing to revise and extend for three years the FFIEC 102, which is currently an approved collection of information for each agency.

Report Title: Market Risk Regulatory Report for Institutions Subject to the Market Risk Capital Rule.

Form Number: FFIEC 102.

Frequency of Response: Quarterly.

Affected Public: Business or other for-profit.

OCC:

OMB Control No.: 1557–0325.

Estimated Number of Respondents: 12 national banks and federal savings associations.

Estimated Burden per Response: 12 burden hours per quarter to file.

Estimated Total Annual Burden: 576 burden hours to file.

Board:

OMB Control No.: 7100–0365.

Estimated Number of Respondents: 31 state member banks, bank holding companies, savings and loan holding companies, and intermediate holding companies.

Estimated Burden per Response: 12 burden hours per quarter to file.

Estimated Total Annual Burden: 1,488 burden hours to file.

FDIC:

OMB Control No.: 3064–0199.

Estimated Number of Respondents: 1 insured state nonmember bank and state savings association.

Estimated Burden per Response: 12 burden hours per quarter to file.

Estimated Total Annual Burden: 48 burden hours to file.

General Description of Report

This quarterly information collection is mandatory for market risk institutions, defined for this purpose as those institutions that are subject to the market risk capital rule as incorporated into Subpart F of the agencies' regulatory capital rules (market risk institutions).[1] All data reported in the FFIEC 102 are available to the public. Each market risk institution is required to file the FFIEC 102 for the agencies' use in assessing the reasonableness and accuracy of the institution's calculation of its minimum capital requirements under the market risk capital rule and in evaluating the institution's capital in relation to its risks. Additionally, the market risk information collected in the FFIEC 102: (a) Permits the agencies to monitor the market risk profile of and evaluate the impact and competitive implications of the market risk capital rule on individual market risk institutions and the industry as a whole; (b) provides the most current statistical data available to identify areas of market risk on which to focus for onsite and offsite examinations; (c) allows the agencies to assess and monitor the levels and components of each reporting institution's risk-based capital requirements for market risk and the adequacy of the institution's capital under the market risk capital rule; and (d) assists market risk institutions in validating their implementation of the market risk framework.

Discussion of Proposed Revisions

1. Reporting the Legal Entity Identifier

The Legal Entity Identifier (LEI) is a 20-digit alpha-numeric code that uniquely identifies entities that engage in financial transactions. The recent financial crisis spurred the development of a Global LEI System (GLEIS). Internationally, regulators and market participants have recognized the importance of the LEI as a key improvement in financial data systems. The Group of Twenty (G–20) nations directed the Financial Stability Board to lead the coordination of international regulatory work and deliver concrete recommendations on the GLEIS by mid-2012, which in turn were endorsed by the G–20 later that same year. In January 2013, the LEI Regulatory Oversight Committee (ROC), which includes regulators from around the world, was established to oversee the GLEIS on an interim basis. With the establishment of the full Global LEI Foundation in 2014, the ROC continues to review and develop broad policy standards for LEIs. The OCC, the Board, and the FDIC are all members of the ROC.

The LEI system is designed to facilitate several financial stability objectives, including the provision of higher quality and more accurate financial data. In the United States, the Financial Stability Oversight Council (FSOC) has recommended that regulators and market participants continue to work together to improve the quality and comprehensiveness of financial data both nationally and globally. In this regard, the FSOC also has recommended that its member agencies promote the use of the LEI in reporting requirements and rulemakings, where appropriate.[2]

Effective beginning October 31, 2014, the Board started requiring holding companies to provide their LEI on the cover pages of the FR Y–6, FR Y–7, and FR Y–10 reports[3] only if a holding company already has an LEI. Thus, if a reporting holding company does not have an LEI, it is not required to obtain one for purposes of these Board reports. Additionally, effective for December 2015, the Board expanded the collection of the LEI to all holding company subsidiary banking and nonbanking legal entities reportable on certain schedules of the FR Y–10 and in one section of the FR Y–6 and FR Y–7 if an LEI has already been issued for the reportable entity.[4] With respect to the FFIEC 102, the agencies are proposing to have reporting institutions provide their LEI on the cover page of each report beginning December 31, 2016, only if an institution already has an LEI. As with the Board reports, an institution that does not have an LEI would not be required to obtain one for purposes of reporting it on the FFIEC 102.

2. Changes to the Board's Respondent Panel

On December 14, 2012, the Board invited comment on a notice of proposed rulemaking (proposed Regulation YY)[5] that would have required a Foreign Banking Organization (FBO) with $50 billion in non-branch assets to establish a U.S. IHC, imposed enhanced prudential standards on the U.S. IHC, and required the U.S. IHC to submit any reporting forms in the same manner and to the same extent as a bank holding company. On February 18, 2014, the Board adopted a final rule implementing enhanced prudential standards for FBOs (Regulation YY),[6] with certain revisions in response to comments. The Board indicated in the preamble to Regulation YY that it would address the reporting requirements for U.S. IHCs at a later date. Accordingly, based on the background provided above, the agencies propose to add U.S. IHCs that are subject to the market risk capital rule to the FFIEC 102 panel of Board respondents.[7] For such U.S. IHCs, the agencies are proposing to implement these changes beginning with the December 31, 2016, report date.

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[1] 12 CFR 3.201 (OCC); 12 CFR 217.201 (Board); and 12 CFR 324.201 (FDIC). The market risk capital rule generally applies to any banking institution with aggregate trading assets and trading liabilities equal to (a) 10 percent or more of quarter-end total assets or (b) $1 billion or more. The statutory provisions that grant the agencies the authority to impose capital requirements are 12 U.S.C. 161 (national banks), 12 U.S.C. 324 (state member banks), 12 U.S.C. 1844(c) (bank holding companies), 12 U.S.C. 1467a(b) (savings and loan holding companies), 12 U.S.C. 5365 (U.S. intermediate holding companies), 12 U.S.C. 1817 (insured state nonmember commercial and savings banks), and 12 U.S.C. 1464 (savings associations).

[2] Financial Stability Oversight Council 2015 Annual Report, page 14, *http://www.treasury.gov/initiatives/fsoc/studies-reports/Documents/2015%20FSOC%20Annual%20Report.pdf.*

[3] FR Y–6, Annual Report of Holding Companies; FR Y–7, Annual Report of Foreign Banking Organizations; and FR Y–10, Report of Changes in Organizational Structure (OMB No. 7100–0297).

[4] 80 FR 38202 (July 2, 2015).

[5] 77 FR 76628 (December 28, 2012).

Request for Comment

Public comment is requested on all aspects of this joint notice. Comments are invited on:

(a) Whether the collections of information that are the subject of this notice are necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

(b) The accuracy of the agencies' estimates of the burden of the information collections as they are proposed to be revised, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide the information.

Comments submitted in response to this joint notice will be shared among the agencies and will be summarized or included in the agencies' requests for OMB approval. All comments will become a matter of public record.

Dated: June 20, 2016.

Stuart Feldstein,

Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System, June 24, 2016.

Robert deV. Frierson,

Secretary of the Board.

Dated at Washington, DC, this 20 day of June 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–15846 Filed 7–1–16; 8:45 am]

BILLING CODE 6210–01–P; 4810–33–P; 6714–01–P

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[6] 79 FR 17240 (March 27, 2014).

[7] In general, U.S. IHCs are subject to the market risk capital rule based on the same criteria used for other banking organizations. *See* 12 CFR 217.201(b)(1); 12 CFR 252.153(e)(2).

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0096; Docket No. 2016–0053; Sequence No. 31]

Information Collection; Patents

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning patents.

DATES: Submit comments on or before September 6, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0096, Patents, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for "9000–0096; Patents". Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0096, Patents". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0096, Patents" on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), IC 9000–0096, 1800 F Street NW., Washington, DC 20405.

Instructions: Please submit comments only and cite Information Collection 9000–0096, Patents, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Charles Gray, Procurement Analyst, Federal Acquisition Policy Division, at 703–795–6328 or email *charles.gray@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The patent coverage in Federal Acquisition Regulation (FAR) subpart 27.2 requires the contractor to report each notice of a claim of patent or copyright infringement that came to the contractor's attention in connection with performing a Government contract (FAR 27.202–1 and 52.227–2).

The contractor is also required to report all royalties anticipated or paid in excess of $250 for the use of patented inventions by furnishing the name and address of licensor, date of license agreement, patent number, brief description of item or component, percentage or dollar rate of royalty per unit, unit price of contract item, and number of units (FAR 27.202–5, 52.227–6, and 52.227–9).

B. Annual Reporting Burden

Number of Respondents: 107.
Responses per Respondent: 1.
Total Annual Responses: 107.
Hours per Response: 1.17.
Estimated Total Burden Hours: 126.
Frequency: On Occasion.
Affected Public: Businesses or other-for-profit entities and not-for-profit institutions.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0096, Patents, in all correspondence.

Dated: June 28, 2016.

Mahruba Uddowla,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–15723 Filed 7–1–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Notice of Intent To Award a Single Source Non-Competing Supplement to the Residential Information Systems Project, University of Minnesota

AGENCY: Administration for Community Living, HHS.

SUMMARY: The Administration for Community Living (ACL) is announcing supplemental funding for the Residential Information Systems Project (RISP) at the University of Minnesota. The RISP project collects and examines national and state by state statistics on all residential services and supports from different sources. Between 2011 and 2016 the Administration on Intellectual and Developmental Disabilities (AIDD) funded the Family Information Systems Project (FISP) to examine the supports and services provided to families with family members with disabilities residing in the family home. The FISP project has created a user-friendly Web site enabling the data to be easily utilized by the public. The Web site includes the annual reports containing data relating to services provided to families in Fiscal Year 2012, Fiscal Year 2013, Fiscal Year 2014 and Fiscal Year 2015. The Web site also includes the infographics, and chart builder products.

With this supplement, data from the FISP will be incorporated into the RISP and the project will be able to continue the collection and examination of the variables related to supports and services provided to families. Specific activities include: Annual state by state data collection, longitudinal analyses of changes in state utilization and expenditures for children vs adults; development and dissemination of one targeted research to practice brief on FISP findings for families and other stakeholders; ongoing FISP technical assistance and webinars and continuation of web-based dissemination of FISP findings though the FISP Web site. In addition, the RISP project will be able to maintain and build upon the established Web site.

SUPPLEMENTARY INFORMATION:

Program Name: Residential Information Systems Project, University of Minnesota.

Award Amount: $170,000.00.

Statutory Authority: The Developmental Disabilities Assistance and Bill of Rights Act of 2000, Public Law 106–402 (Oct 30, 2000).

Catalog of Federal Domestic Assistance (CFDA) Number: 93.631 Discretionary Projects.

Program Description: The Residential Information Systems Project in one of three longitudinal data collection projects funded by the Administration on Intellectual and Developmental Disabilities, an agency of the U.S. Administration for Community Living. RISP is a study of annual state-by-state and national statistics on residential services and supports for people with intellectual and developmental disabilities. The project includes funding for supports and services from a variety of sources, including public and non-public, Medicaid-funded and non-Medicaid-funded residential and supportive services.

Agency Contact: For further information or comments regarding this supplemental action, contact Katherine Cargill-Willis, U.S. Department of Health and Human Services, Administration for Community Living, Administration for Intellectual and Developmental Disabilities, 330 C Street SW., Washington, DC 20201; telephone 202–795–7322; email *Katherine.cargill-willis@acl.hhs.gov.*

Dated: June 28, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–15852 Filed 7–1–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Intent To Award a Sole Source Supplement to the Christopher and Dana Reeve Foundation

AGENCY: Administration for Community Living.

ACTION: Notice of intent to award a sole source supplement to the Christopher and Dana Reeve Foundation.

SUMMARY: The Administration for Community Living (ACL) is announcing the award of supplemental funding for the National Paralysis Resource Center (PRC) that was included in the 2016 Congressional budget appropriations. The National Paralysis Resource Center is operated by the Christopher and Dana Reeve Foundation, which offers important programmatic opportunities for persons with disabilities and older adults. The PRC provides comprehensive information for people living with spinal cord injury, paralysis, and mobility-related disabilities and their families. Resources include information and referral by phone and email in multiple languages including English and Spanish; a peer and family support mentoring program; a military and veterans program; multicultural outreach services; free lending library; quality of life grants; and a national Web site.

Program Name: National Paralysis Resource Center.

Award Amount: $976,580.

Award Type: Cooperative Agreement.

DATES: The award will be issued for a project period of June 1, 2016 through May 31, 2017.

Statutory Authority: This program is authorized under Section 317 of the Public Health Service Act (42 U.S.C. 247(b–4)); Consolidated and Further Continuing Appropriations Act, 2016, Public Law 114–113 (Dec. 18, 2015). CFDA Number: 93.325 Discretionary Projects.

FOR FURTHER INFORMATION CONTACT: Elizabeth Leef, U.S. Department of Health and Human Services, Administration for Community Living, Independent Living Administration, 330 C Street SW., Washington, DC 20201; telephone 202–475–2482.

SUPPLEMENTARY INFORMATION: The purpose of the supplemental funding is to support the expansion a national Paralysis Resource Center to improve the health and quality of life of individuals living with paralysis and their families by raising awareness of and facilitating access to a broad range of services relevant to individuals with paralysis. This supplemental funding will be used to enhance the PRCs ability to improve performance & evaluation, to collaborate with others organizations and or agencies vested in paralysis to transition people living with paralysis from institutional settings into community living or higher education, and to increase grant opportunities that serve people living with paralysis, their caregivers, and families. With the additional funding, the PRC will work to expand the National Resource and Information Center; increase the health and quality of life of Americans with disabilities living with paralysis; increase support and resources to people with paralysis, their families and caregivers; expand collaboration with federal agencies and other national organizations that have a vested interested in the paralysis community; and strengthen performance measures. This supplemental funding will be made available this fiscal year and in each fiscal year that Congress appropriates additional funding above the current funding level of this existing grant project.

Dated: June 28, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–15853 Filed 7–1–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 14–050: Virtual Consortium for Translational/Transdisciplinary Environmental Research (ViCTER).

Date: July 21, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Martha Garcia, Ph.D., Scientific Reviewer Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, MSC 7818, Bethesda, MD 20892, 301–435–1243, *garciamc@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Multiple Sclerosis and Neurovirology.

Date: July 22, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Samuel C. Edwards, Ph.D., IRG CHIEF, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR13–195: Preclinical Research on Model Organisms to Predict Treatment Outcomes for Disorders Associated with Intellectual and Developmental Disabilities.

Date: July 26, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda, MD 20892, (301) 402–4411, *tianbi@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 16–115: Optimization of Monoclonal Antibodies for Eliminating the HiV Reservoir.

Date: July 27, 2016.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; US-China Program for Collaborative Biomedical Research.

Date: August 1, 2016.

Time: 5:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, (301) 806–2515, *chatterm@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 28, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15735 Filed 7–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Effects of Inhaled Nicotine Review.

Date: July 26, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Baltimore Washington Airport Hotel, 1100 Old Elkridge Landing Road, Linthicum Heights, MD 21090.

Contact Person: Shelley S. Sehnert, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892–7924, 301–435–0303, *ssehnert@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15733 Filed 7–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: July 13–14, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Juraj Bies, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Rm. 4158, MSC 7806, Bethesda, MD 20892, 301–435–1256, *biesj@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Retinal Development, Signaling and Circuitry.

Date: July 15, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mary Custer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, (301) 435–1164, *custerm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Regulation of Organelle Degradation.

Date: July 20, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Janet M. Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7840, Bethesda, MD 20892, 301–806–2765, *larkinja@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Asthma, Pulmonary Fibrosis and Inflammation.

Date: July 26–27, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bradley Nuss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC7814, Bethesda, MD 20892, 301–451–8754, *nussb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Vascular and Hematology AREA application review.

Date: July 28, 2016.

Time: 2:00 p.m. to 4:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkusl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cellular and Molecular Immunology.

Date: July 28, 2016.

Time: 4:00 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Tina McIntyre, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301–594–6375, *mcintyrt@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR16–045: Emerging Epidemic Virus Research Training.

Date: July 29, 2016.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kenneth M. Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3204, MSC 7808, Bethesda, MD 20892, 301–496–6980, *izumikm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; US-China Program for Collaborative Biomedical Research.

Date: August 1, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, (301) 806–2515, *chatterm@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 28, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15736 Filed 7–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; P01 Application Review.

Date: August 9, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6710 B Rockledge Drive, Room 2131D, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710 B Rockledge Drive, Room 2131D, Bethesda, MD 20892, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15731 Filed 7–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Clinical Research on Mind-Body Interventions.

Date: July 29, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, DEMII, 401, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Hungyi Shau, Ph.D., Scientific Review Officer, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, 301–480–9504, *Hungyi.Shau@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: June 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15734 Filed 7–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Sleep Disorders Research Advisory Board. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sleep Disorders Research Advisory Board.

Date: August 18–19, 2016.

Time: August 18, 2016, 1:00 p.m. to 5:00 p.m.

Agenda: To discuss plans for the proposed revision of the NIH Sleep Disorders Research Plan, and potential directions for inter-agency coordination activities.

Place: National Institutes of Health, Two Rockledge Center, Conference Room 9112/9116, 6701 Rockledge Drive, Bethesda, MD 20892–7952.

Time: August 19, 2016, 8:00 a.m. to 3:00 p.m.

Agenda: To discuss plans for the proposed revision of the NIH Sleep Disorders Research Plan, and potential directions for inter-agency coordination activities.

Place: National Institutes of Health, Two Rockledge Center Conference Room 9112/9116, 6701 Rockledge Drive, Bethesda, MD 20892–7952.

Contact Person: Michael J. Twery, Ph.D., Director, National Center on Sleep Disorders Research, Division of Lung Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Suite 10038, Bethesda, MD 20892–7952, 301–435–0199, *twerym@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, 93.840 Translation and Implementation Science for Heart, Lung, Blood Diseases, and Sleep Disorders, National Institutes of Health, HHS)

Dated: June 28, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–15732 Filed 7–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Advisory Committee; Drug Testing Advisory Board; Renewal

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) is announcing the renewal of SAMHSA's Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB).

FOR FURTHER INFORMATION CONTACT: Brian Makela, Division of Workplace Programs, CSAP, SAMHSA, 5600 Fishers Lane, Room 16N02B, Rockville, Maryland 20857, *Telephone:* 240–276–2600, *Fax:* 240–276–2610, *Email: brian.makela@ssamhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB) is authorized by 42 U.S.C. 217a (Section 222 of the Public Health Service Act), as amended. The CSAP DTAB is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C., App., which sets forth standards for the formation and use of advisory committees.

The CSAP DTAB provides advice to the Administrator, SAMHSA, based on an ongoing review of the direction, scope, balance, and emphasis of the Agency's drug testing activities and the drug testing laboratory certification program.

Summer King,

Statistician, Substance Abuse and Mental Health Services Administration.

[FR Doc. 2016–15815 Filed 7–1–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Regulations To Implement SAMHSA's Charitable Choice Statutory Provisions—42 CFR Parts 54 and 54a (OMB No. 0930–0242)—Revision

Section 1955 of the Public Health Service Act (42 U.S.C. 300x–65), as amended by the Children's Health Act of 2000 (Pub. L. 106–310) and Sections 581–584 of the Public Health Service Act (42 U.S.C. 290kk *et seq.*, as added by the Consolidated Appropriations Act (Pub. L. 106–554)), set forth various provisions which aim to ensure that religious organizations are able to compete on an equal footing for federal funds to provide substance abuse services. These provisions allow religious organizations to offer substance abuse services to individuals without impairing the religious character of the organizations or the religious freedom of the individuals who receive the services. The provisions apply to the Substance Abuse Prevention and Treatment Block Grant (SABG), to the Projects for Assistance in Transition from Homelessness (PATH) formula grant program, and to certain Substance Abuse and Mental Health Services Administration (SAMHSA) discretionary grant programs (programs that pay for substance abuse treatment and prevention services, not for certain infrastructure and technical assistance activities). Every effort has been made to assure that the reporting, recordkeeping and disclosure requirements of the proposed regulations allow maximum flexibility in implementation and impose minimum burden.

No changes are being made to the regulations; just a decrease in the burden hours.

Information on how states comply with the requirements of 42 CFR part 54 was approved by the Office of Management and Budget (OMB) as part of the Substance Abuse Prevention and Treatment Block Grant FY 2016–2017 annual application and reporting requirements approved under OMB control number 0930–0168.

42 CFR Citation and Purpose	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
Part 54—States Receiving SA Block Grants and/or Projects for Assistance in Transition from Homelessness (PATH)					
Reporting:					
96.122(f)(5) Annual report of activities the state undertook to comply 42 CFR Part 54 (SABG).	60	1	60	1	60
54.8(c)(4) Total number of referrals to alternative service providers reported by program participants to States (respondents).					
SABG	6	23 (avg.)	135	1	135
PATH	10	5	50	1	50
54.8 (e) Annual report by PATH grantees on activities undertaken to comply with 42 CFR Part 54.	56	1	56	1	56
Disclosure:					
54.8(b) State requires program participants to provide notice to program beneficiaries of their right to referral to an alternative service provider.					
SABG	60	1	60	.05	3
PATH	56	1	56	.05	3
Recordkeeping:					
54.6(b) Documentation must be maintained to demonstrate significant burden for program participants under 42 U.S.C. 300x–57 or 42 U.S.C. 290cc–33(a)(2) and under 42 U.S.C. 290cc–21 to 290cc–35.	60	1	60	1	60
Part 54—Subtotal	115		477		367
Part 54a—States, local governments and religious organizations receiving funding under Title V of the PHS Act for substance abuse prevention and treatment services					
Reporting:					
54a.8(c)(1)(iv) Total number of referrals to alternative service providers reported by program participants to states when they are the responsible unit of government.	25	4	100	.083	8
54a(8)(d) Total number of referrals reported to SAMHSA when it is the responsible unit of government. (NOTE: This notification will occur during the course of the regular reports that may be required under the terms of the funding award.).	20	2	40	.25	10
Disclosure:					

42 CFR Citation and Purpose	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
54a.8(b) Program participant notice to program beneficiaries of rights to referral to an alternative service provider.	1,460	1	1,460	1	1,460
Part 54a—Subtotal	1,505		1,600		1,478
Total	1,620		2,077		1,845

Written comments and recommendations concerning the proposed information collection should be sent by August 4, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2016–15816 Filed 7–1–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF TRANSPORTATION

Office of the Assistant Secretary for Research and Technology

DEPARTMENT OF DEFENSE

U.S. Army Corps of Engineers

[DOT–OST–2015–0105]

Nationwide Differential Global Positioning System (NDGPS)

AGENCY: DHS—Coast Guard, DOT—Office of the Assistant Secretary for Research and Technology (OST–R), and DOD—U.S. Army Corps of Engineers, Office of Engineering and Construction.

ACTION: Notice.

SUMMARY: The United States Coast Guard (USCG), U.S. Department of Transportation (DOT), and United States Army Corps of Engineers (USACE) published a notice on August 18, 2015 seeking public comments on the proposed shutdown and decommissioning of 62 the then-existing 84 Nationwide Differential Global Positioning System (NDGPS) sites. After a review of the comments received, we have reduced to 37 the number of NDGPS sites to be shutdown, 9 of which are USCG Maritime sites and 28 of which are DOT inland sites. As a result of this action, the NDGPS system will remain operational with a total of 46 USCG and USACE sites available to users in the maritime and coastal regions.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, contact CAPT Scott Smith, Coast Guard, telephone (202) 372–1545 or email *scott.j.smith2@uscg.mil;* or James Arnold, U.S. DOT OST–R, NDGPS Program Manager, telephone (202) 366–8422 or email *NDGPS@dot.gov*.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The USCG began development of the Maritime Differential Global Positioning System (MDGPS) in the late 1980s. In 1994, the USCG published a **Federal Register** notice (59 FR 13757; March 23, 1994) discussing the accuracy limitations in the GPS system, and informing the public that the USCG's Differential GPS Service would be implemented for harbor and harbor approach areas by 1996. The USCG's Maritime DGPS system used land-based reference stations to enhance the accuracy of GPS to the International Maritime Organization (IMO) harbor approach standard for near-coastal maritime navigation. Through Presidential Decision Directive NSTC–6, U.S. Global Positioning System Policy, (March 28, 1996) the President designated the U.S. Department of Transportation as the Nation's "lead agency for all Federal civil GPS matters." The Directive further required the USDOT to "develop and implement U.S. Government augmentation to the basic GPS for transportation applications." The USCG's Maritime DGPS Service was established as an augmentation to GPS to aid maritime navigation in certain harbors and harbor approach areas. Enacted on October 27, 1997, Section 346 of the Department of Transportation and Related Agencies Appropriations Act of 1998, Public Law 105–66, 111 Stat. 1425, authorized the USDOT to establish, operate and manage the NDGPS system. Furthermore, section 346 authorized the Secretary to integrate the USCG's existing Maritime DGPS reference stations with the NDGPS, and to ensure System compatibility with the Continuously Operating Reference Stations (CORS) network, which had been independently established by the National Geodetic Survey.

Pursuant to this statutory authority, the Secretary established 29 inland DGPS sites, which along with the USCG's Maritime DGPS sites, and seven sites established by the U.S. Army Corps of Engineers (USACE), collectively comprised the Nationwide DGPS (NDGPS) system. Pursuant to a 1999 delegation of authority from the Secretary of Transportation (64 FR 7813; February 17, 1999), the Commandant of the USCG was designated as lead for implementation, operation, and maintenance of the NDGPS service. The Secretary retained authority for System requirements and associated responsibilities under the National Environmental Policy Act (NEPA), and assumed the role of NDGPS sponsor and chair of the multi-agency NDGPS Policy and Implementation Team (PIT), which directs the overall management of the NDGPS system.

Since its establishment in the late 1990s, several factors have contributed to the stagnation of transportation-related use of NDGPS, including lack of a regulatory requirement for vessels to carry DGPS equipment within U.S. territorial waters, technological advances in GPS that have increased its accuracy, increased reliability of other GPS augmentation systems that do not require a second receiver, limited availability of consumer-grade DGPS radio beacon receivers, and the discontinuance of GPS Selective Availability.

On August 18, 2015, USCG, DOT, and USACE published a notice in the **Federal Register** seeking public comments on the proposed shutdown and decommissioning of 62 NDGPS sites on January 15, 2016 (see 80 FR 50018). The DHS, DOT, and USACE received 168 comments in response to the notice, several of which were duplicate entries. Due to the number and nature of comments received, the USCG, DOT, and USACE decided to postpone the proposed closing of the sites until the comments were thoroughly reviewed. As a result of our analysis of these comments, which is discussed below, we determined that only 37 of the 62 sites proposed will be shut down and decommissioned, leaving a total of 46 USCG and USACE sites that will continue to provide single-site coverage for the maritime areas currently covered by the USCG and USACE. Termination of the NDGPS broadcast at the sites listed below is planned to occur 30 days after the publication of this notice in the **Federal Register**.

Discussion of Comments

Inland Coverage

Several comments were received that addressed the inland portion on NDGPS but none identified a Federal transportation requirement. The determination to shut down 28 inland NDGPS sites reflects the lack of a federal transportation requirement to maintain a DGPS signal at these sites in response to the August 2015 **Federal Register** Notice and limited availability of consumer-grade NDGPS radiobeacon receivers.

Continuously Operating Reference Station Comments

Almost half of the received comments requested that particular sites remain open as a data source to support surveying, science, and natural resource management. Each of the NDGPS sites announced for closure in the August 2015 Notice also serves as a Continuously Operating Reference Station (CORS) data source. The CORS network contains approximately 2000 individual sites owned and operated by almost 200 different public and private entities. The CORS data is principally used by scientists, surveyors and engineers to improve the precision of GPS data. Additionally, natural resource agencies also rely on the CORS sites in the management and oversight of national parks, forestry and agriculture. Each CORS site provides data via the Internet to the National Geodetic Survey, which analyzes the data and then distributes it to the public free of charge. The science, land surveying and engineering professionals who utilize the CORS system to refine three-dimensional position data do not use the DGPS radio broadcast signal developed and operated for surface and maritime transportation purposes.

The USCG will consider the transfer of ownership and or operational control of the below-listed NDGPS sites to private entities or other Federal, State, and/or local agencies interested in continuing to operate them as CORS sites. Questions about potential transfer of specific CORS sites should be directed to the individual(s) referenced in the **FOR FURTHER INFORMATION CONTACT** section above.

Maritime Coverage

Approximately one third of the comments received came from maritime users of the NDGPS system, including marine pilots, dredging companies and marine surveyors or hydrographers, who urged the USCG and USACE to retain the existing maritime sites. 58 of these maritime comments addressed specific maritime DGPS uses and advocated for retaining DGPS sites. 44 of the 58 comments expressed a need for enhanced precision for navigation provided by DGPS (*e.g.* piloting) and 14 of the 58 comments expressed a need for enhanced precision for positioning to support marine surveying and dredging. Commenting parties included regional and national associations of maritime pilots and professionals as well as both U.S. (USACE, NPA, NOAA) and foreign government agencies (Canada and United Kingdom). Based upon these comments, USACE elected to not close any of its DGPS sites. For similar reasons, the USCG determined that it will retain all but nine of its existing sites and will only close sites where another site already provides coverage or where no maritime users expressed a need to keep the site open. As a result, the USCG's maritime DGPS system will remain largely intact. However, certain locations will no longer have DGPS coverage from multiple sites. With the exception of Puerto Rico and Cold Bay, Alaska, where the USCG will no longer provide DGPS coverage due to a lack of expressed need, the remaining USCG system will provide single-site DGPS coverage for port and harbor approaches in all areas currently covered by single or multiple-site coverage.

General Comments

An additional 16 comments expressed a general interest in retaining the system without specifying a discrete use or application requiring the service to remain intact. Another 6 comments were provided on behalf of standards bodies and advocacy organizations regarding potential application of NDGPS infrastructure for future complementary positioning, navigation and timing systems (*e.g.* eLoran and R-Mode).

After evaluating the feedback received, USCG and USACE will retain more sites than were originally proposed for retention in the August 2015 **Federal Register** Notice to continue providing DGPS coverage to maritime users, while reducing coverage redundancies and coverage to areas where no maritime interests expressed a need for continued operation. The reduced system will continue to provide DGPS services for precision maritime navigation, marine surveying, and dredging as we continue to research and assess DGPS use and alternatives based upon advances in GPS precision and augmentation technology.

Sites To Be Disestablished

Termination of the NDGPS broadcast at the following sites is planned to occur 30 days after the publication of this notice in the **Federal Register**.

List of Maritime Sites To Be Disestablished

- Brunswick, ME
- Cold Bay, AK
- Eglin, FL
- Isabela, PR
- Lompoc, CA
- Pickford, MI
- Saginaw Bay, MI
- Sturgeon Bay, WI
- Key West, FL

List of Inland Sites To Be Disestablished

- Albuquerque, NM
- Austin, NV
- Bakersfield, CA
- Billings, MT
- Chico, CA
- Clark, SD
- Dandridge, TN
- Essex, CA
- Flagstaff, AZ
- Greensboro, NC
- Hackleburg, AL
- Hagerstown, MD
- Hartsville, TN
- Hawk Run, PA
- Klamath Falls, OR
- Macon, GA
- Medora, ND
- Myton, UT
- Pine River, MN
- Polson, MT
- Pueblo, CO
- Savannah, GA
- Seneca, OR
- Spokane, WA

- St. Marys, WV
- Summerfield, TX
- Topeka, KS
- Whitney, NE

Graphics depicting the proposed changes to NDGPS coverage are available at the USCG's NDGPS General Information Web site at: *http://www.navcen.uscg.gov/?pageName=dgpsMain.*

For more information on the NDGPS Service, visit the USCG's Web site at *http://www.navcen.uscg.gov/?pageName=dgpsMain.*

Additional information on GPS, NDGPS, and other GPS augmentation systems is also available in the 2014 Federal Radionavigation Plan, published by the Department of Defense, DHS, and DOT, which is also available at the USCG's Web site at *http://www.navcen.uscg.gov/?pageName=pubsMain.*

Authority

This notice is issued under the authority of 5 U.S.C. 552(a), 14 U.S.C. 81, and 49 U.S.C. 301 (Pub. L. 105–66, section 346).

Issued in Washington, DC, on June 21, 2016.

CAPT David C. Barata,

Director of Marine Transportation Systems, Acting U.S. Coast Guard.

Mr. Gregory D. Winfree,

Assistant Secretary for Research and Technology, U.S. Department of Transportation.

James C. Dalton,

Chief, Engineering and Construction, U.S. Army Corps of Engineers.

[FR Doc. 2016–15886 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0083]

Agency Information Collection Activities: United States-Caribbean Basin Trade Partnership Act (CBTPA)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: United States-Caribbean Basin Trade Partnership Act (CBTPA) (Form 450). CBP is proposing that this information collection be extended with a change to the burden hours. There is no change to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before September 6, 2016 to be assured of consideration.

ADDRESSES: Written comments may be mailed to U.S. Customs and Border Protection, Attn: Paperwork Reduction Act Officer, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, or by telephone at 202–325–0123 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs please contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP Web site at *https://www.cbp.gov/.* For additional help: *https://help.cbp.gov/app/home/search/1.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: United States-Caribbean Basin Trade Partnership Act.

OMB Number: 1651–0083.

Form Number: CBP Form 450.

Abstract: The provisions of the United States-Caribbean Basin Trade Partnership Act (CBTPA) were adopted by the U.S. with the enactment of the Trade and Development Act of 2000 (Pub. L. 106–200). The objective of the CBTPA is to expand trade benefits to countries in the Caribbean Basin. For preferential duty treatment under CBTPA, importers are required to have a CBTPA Certification of Origin (CBP Form 450) in their possession at the time of the claim, and to provide it to CBP upon request. CBP Form 450 collects data such as contact information for the exporter, importer and producer, and information about the goods being claimed.

This collection of information is provided for by 19 CFR 10.224. CBP Form 450 is accessible at: *http://forms.cbp.gov/pdf/CBP_Form_450.pdf.*

Current Actions: This submission is being made to extend the expiration date and to revise the burden hours as a result of an increase in time estimated per response from 15 minutes to 2 hours. There are no changes CBP Form 450 or to the data collected on this form.

Type of Review: Extension with a change to the burden hours.

Affected Public: Businesses.

Estimated Number of Respondents: 15.

Estimated Number of Responses per Respondent: 286.13.

Estimated Total Annual Responses: 4,292.

Estimated Time per Response: 2 hours.

Estimated Total Annual Burden Hours: 8,584.

Dated: June 29, 2016.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2016–15785 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4272–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4272–DR), dated June 11, 2016, and related determinations.

DATES: *Effective Date:* June 24, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective June 24, 2016.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15820 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1548]

Proposed Flood Hazard Determinations for Carroll County, Iowa and Incorporated Areas; Withdrawal

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed notice; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is withdrawing its proposed notice concerning proposed flood hazard determinations, which may include the addition or modification of any Base Flood Elevation, base flood depth, Special Flood Hazard Area boundary or zone designation, or regulatory floodway (herein after referred to as proposed flood hazard determinations) on the Flood Insurance Rate Maps and, where applicable, in the supporting Flood Insurance Study reports for Carroll County, Iowa and Incorporated Areas.

DATES: This withdrawal is effective on July 5, 2016.

ADDRESSES: You may submit comments, identified by Docket No. FEMA–B–1548 to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: On January 19, 2016, FEMA published a proposed notice at 81 FR 2889, proposing flood hazard determinations for Carroll County, Iowa and Incorporated Areas. FEMA is withdrawing the proposed notice.

Authority: 42 U.S.C. 4104; 44 CFR 67.4.

Dated: May 19, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2016–15764 Filed 7–1–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of June 6, 2016, which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: May 19, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Lower Wisconsin River Watershed	
Dane County, Wisconsin and Incorporated Areas **Docket No.: FEMA–B–1426**	
Unincorporated Areas of Dane County	City County Building, 210 Martin Luther King Jr. Boulevard #116, Madison, WI 53703.
Village of Belleville	Village Hall, 24 West Main Street, Belleville, WI 53508.
Village of Black Earth	Village Hall, 1210 Mills Street, Black Earth, WI 53515.
Village of Cross Plains	Village Hall, 2417 Brewery Road, Cross Plains, WI 53528.
Village of Mazomanie	Village Hall, 133 Crescent Street, Mazomanie, WI 53560.

II. Non-watershed-based studies:

Community	Community map repository address
Yakima County, Washington and Incorporated Areas **Docket No.: FEMA–B–1415**	
City of Union Gap	City Hall, 102 West Ahtanum Road, Union Gap, WA 98903.
City of Yakima	City Hall, 129 North 2nd Street, Yakima, WA 98901.
Confederated Tribes and Bands of the Yakama Nation	Yakama Nation Offices, 401 Fort Road, Toppenish, WA 98948.
Unincorporated Areas of Yakima County	Yakima County Public Services, 128 North 2nd Street, Yakima, WA 98901.

[FR Doc. 2016–15749 Filed 7–1–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4269–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Texas (FEMA–4269–DR), dated April 25, 2016, and related determinations.

DATES: Effective Date: May 23, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Kevin L. Hannes as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15812 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4273–DR; Docket ID FEMA–2016–0001]

West Virginia; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of West Virginia (FEMA–4273–DR), dated June 25, 2016, and related determinations.

DATES: *Effective Date:* June 28, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of West Virginia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 25, 2016.

Clay, Fayette, Monroe, Roane, and Summers Counties for Individual Assistance.

Clay, Fayette, Monroe, Roane, and Summers Counties for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15823 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: May 19, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Alabama:					
Jefferson (FEMA Docket No.: B–1600).	Unincorporated areas of Jefferson County (15–04–9295P).	The Honorable Jimmie Stephens, Chairman, Jefferson County Commission, 716 Richard Arrington Jr. Boulevard, North Birmingham, AL 35203.	Jefferson County Land Development Department, 716 Richard Arrington Jr. Boulevard, North Birmingham, AL 35203.	April 14, 2016 ..	010217
Colorado:					
Denver (FEMA Docket No.: B–1600).	City and County of Denver (15–08–0294P).	The Honorable Michael B. Hancock, Mayor, City and County of Denver, 1437 Bannock Street, Suite 350, Denver, CO 80202.	Department of Public Works, 201 West Colfax Avenue, Denver, CO 80202.	April 15, 2016 ..	080046
Fremont (FEMA Docket No.: B–1600).	Town of Williamsburg (15–08–0985P).	The Honorable Joshua Baker, Mayor, Town of Williamsburg, 1 John Street, Williamsburg, CO 81226.	City Hall, 1 John Street, Williamsburg, CO 81226.	April 14, 2016 ..	080028
Fremont (FEMA Docket No.: B–1600).	Unincorporated areas of Fremont County (15–08–0985P).	The Honorable Ed Norden, Chairman, Fremont County Board of Commissioners, 615 Macon Avenue, Canon City, CO 81212.	Fremont County Administrator's Office, 615 Macon Avenue, Canon City, CO 81212.	April 14, 2016 ..	080067
Jefferson (FEMA Docket No.: B–1600).	City of Lakewood (15–08–0294P) ..	The Honorable Bob Murphy, Mayor, City of Lakewood, Lakewood Civic Center South, 480 South Allison Parkway, Lakewood, CO 80226.	Public Works Department, Lakewood Civic Center North, 480 South Allison Parkway, Lakewood, CO 80226.	April 15, 2016 ..	085075
Larimer (FEMA Docket No.: B–1600).	City of Fort Collins (15–08–1293P)	The Honorable Wade Troxell, Mayor, City of Fort Collins, P.O. Box 580, Fort Collins, CO 80522.	Stormwater Utilities Department, 700 Wood Street, Fort Collins, CO 80521.	March 28, 2016	080102
Delaware: New Castle (FEMA Docket No.: B–1600).	Unincorporated areas of New Castle County (14-03-3246P).	The Honorable Thomas P. Gordon, New Castle County Executive, 87 Reads Way, New Castle, DE 19720.	New Castle County Land Use Department, 87 Reads Way, New Castle, DE 19720.	April 15, 2016 ..	105085
Florida:					
Lee (FEMA Docket No.: B–1600).	Unincorporated areas of Lee County (15–04–9971X).	The Honorable Brian Hamman, Chairman, Lee County Board of Commissioners, P.O. Box 398, Fort Myers, FL 33902.	Lee County Planning and Zoning Department, 1500 Monroe Street, Fort Myers, FL 33901.	March 30, 2016	125124
Miami-Dade (FEMA Docket No.: B–1600).	City of Miami (15-04-9564P)	The Honorable Tomás P. Regalado, Mayor, City of Miami, 3500 Pan American Drive, Miami, FL 33133.	Building Department, 444 Southwest 2nd Avenue, 4th Floor, Miami, FL 33130.	March 22, 2016	120650
Osceola (FEMA Docket No.: B–1600).	City of Kissimmee (14-04-A481P) ..	The Honorable Jim Swan, Mayor, City of Kissimmee, 101 Church Street, Kissimmee, FL 34741.	Engineering Department, 101 Church Street, Kissimmee, FL 34741.	April 15, 2016 ..	120190
Osceola (FEMA Docket No.: B–1600).	Unincorporated areas of Osceola County (14-04-A481P).	The Honorable Brandon Arrington, Chairman, Osceola County Board of Commissioners, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Stormwater Department, 1 Courthouse Square, Suite 3100, Kissimmee, FL 34741.	April 15, 2016 ..	120189
St. Johns, (FEMA Docket No.: B–1600).	Unincorporated areas of St. Johns County (15–04–9919P).	The Honorable Rachael L. Bennett, Chair, St. Johns County Board of Commissioners, 500 San Sebastian View, St. Augustine, FL 32084.	St. Johns County Building Services Division, 4040 Lewis Speedway, St. Augustine, FL 32084.	April 13, 2016 ..	125147
Georgia: Columbia (FEMA Docket No.: B–1605).	Unincorporated areas of Columbia County (15–04–7397P).	The Honorable Ron C. Cross, Chairman, Columbia County Board of Commissioners, P.O. Box 498, Evans, GA 30809.	Columbia County Engineering Services Department, 630 Ronald Reagan Drive, Building A, East Wing, Evans, GA 30809.	March 31, 2016	130059
Massachusetts:					

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Plymouth (FEMA Docket No.: B–1605).	Town of Lakeville (15–01–2489P) ..	The Honorable Aaron Burke, Chairman, Town of Lakeville Board of Selectmen, 346 Bedford Street, Lakeville, MA 02347.	Town Hall, 346 Bedford Street, Lakeville, MA 02347.	March 25, 2016	250271
Plymouth (FEMA Docket No.: B–1605).	Town of Middleborough (15–01–2489P).	The Honorable Allin Frawley, Chairman, Town of Middleborough Board of Selectmen, 10 Nickerson Avenue, Middleborough, MA 02346.	Planning Department, Town Hall Annex, 20 Centre Street, Middleborough, MA 02346.	March 25, 2016	250275
Plymouth (FEMA Docket No.: B–1605).	Town of Rochester (15–01–2489P)	The Honorable Richard D. Nunes, Chairman, Town of Rochester Board of Selectmen, 1 Constitution Way, Rochester, MA 02770.	Town Hall Annex, 37 Marion Road, Rochester, MA 02770.	March 25, 2016	250280
North Carolina:					
Haywood (FEMA Docket No.: B–1600).	Unincorporated areas of Haywood County (15–04–9975P).	The Honorable Mark S. Swanger, Chairman, Haywood County Board of Commissioners, 215 North Main Street, Waynesville, NC 28786.	Haywood County Planning Department, 157 Paragon Parkway, Suite 200, Clyde, NC 28721.	April 5, 2016	370120
Orange (FEMA Docket No.: B–1607).	Town of Chapel Hill (15–04–3876P)	The Honorable Pam Hemminger, Mayor, Town of Chapel Hill, 405 Martin Luther King Jr. Boulevard, Chapel Hill, NC 27514.	Public Works Department, Stormwater Division, 405 Martin Luther King Jr. Boulevard, Chapel Hill, NC 27514.	April 4, 2016	370180
Oklahoma: Tulsa (FEMA Docket No.: B–1605).	City of Tulsa (15–06–0947P)	The Honorable Dewey Bartlett, Jr., Mayor, City of Tulsa, 175 East 2nd Street, Tulsa, OK 74103.	Development Services Department, 175 East 2nd Street, Tulsa, OK 74103.	April 15, 2016 ..	405381
Pennsylvania: Delaware (FEMA Docket No.: B–1605).	Township of Haverford (15–03–2347P).	The Honorable Lawrence J. Gentile, Manager, Township of Haverford, 2325 Darby Road, Havertown, PA 19083.	Department of Community Development, 2325 Darby Road, Havertown, PA 19083.	March 14, 2016	420417
South Carolina:					
Charleston (FEMA Docket No.: B–1600).	City of Charleston (15-04-9773P) ...	The Honorable Joseph P. Riley, Jr., Mayor, City of Charleston, P.O. Box 652, Charleston, SC 29402.	Building Inspections Department, 2 George Street, Charleston, SC 29401.	March 28, 2016	455412
Greenville (FEMA Docket No.: B–1605).	Unincorporated areas of Greenville County (15–04–5639P).	The Honorable Bob Taylor, Chairman, Greenville County Council, 301 University Ridge, Suite 2400, Greenville, SC 29601.	Greenville County Planning and Code Compliance Department, 301 University Ridge, Suite 4100, Greenville, SC 29601.	March 18, 2016	450089
York (FEMA Docket No.: B–1605).	City of Rock Hill (15–04–2163P)	The Honorable Doug Echols, Mayor, City of Rock Hill, 155 Johnston Street, Suite 210, Rock Hill, SC 29730.	City Hall, 155 Johnston Street, Suite 300, Rock Hill, SC 29730.	March 29, 2016	450196
York (FEMA Docket No.: B–1605).	Unincorporated areas of York County (15–04–2163P).	The Honorable J. Britt Blackwell, Chairman, York County Council, 6 South Congress Street, York, SC 29745.	York County Heckle Complex, 1070 Heckle Boulevard, Suite 107, York, SC 29732.	March 29, 2016	450193
South Dakota:					
Codington (FEMA Docket No.: B–1600).	City of Watertown (15-08-0555P) ...	The Honorable Steve Thorson, Mayor, City of Watertown, 23 2nd Street Northeast, Watertown, SD 57201.	City Hall, 23 2nd Street Northeast, Watertown, SD 57201.	March 22, 2016	460016
Codington (FEMA Docket No.: B–1600).	Unincorporated areas of Codington County (15-08-0555P).	The Honorable Elmer Brinkman, Chairman, Codington County Board of Commissioners, 14 1st Avenue Southeast, Watertown, SD 57201.	Codington County Planning and Zoning Department, 1910 West Kemp Avenue, Watertown, SD 57201.	March 22, 2016	460260
Tennessee:					
Fayette (FEMA Docket No.: B–1605).	Town of Oakland (15–04–9364P) ...	The Honorable Chris Goodman, Mayor, Town of Oakland, P.O. Box 56, Oakland, TN 38060.	Building Department, 75 Clay Street, Oakland, TN 38060.	March 31, 2016	470418

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Fayette (FEMA Docket No.: B–1605).	Unincorporated areas of Fayette County (15–04–9364P).	The Honorable Rhea Taylor, Mayor, Fayette County, P.O. Box 218, Somerville, TN 38068.	Fayette County Planning and Development Department, 16265 U.S. Highway 64, Somerville, TN 38068.	March 31, 2016	470352
Texas:					
Bell (FEMA Docket No.: B–1600).	City of Temple (15-06-3320P)	The Honorable Danny Dunn, Mayor, City of Temple, 2 North Main Street, Suite 103, Temple, TX 76501.	Engineering Department, 3210 East Avenue H, Building A, Suite 107, Temple, TX 76501.	April 12, 2016 ..	480034
Bexar (FEMA Docket No.: B–1605).	Unincorporated areas of Bexar County (15–06–1291P).	The Honorable Nelson W. Wolff, Bexar County Judge, Paul Elizondo Tower, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207.	March 30, 2016	480035
Collin (FEMA Docket No.: B–1600).	City of Frisco (15-06-1583P)	The Honorable Maher Maso, Mayor, City of Frisco, 6101 Frisco Square Boulevard, Frisco, TX 75034.	Engineering Services Department, 6101 Frisco Square Boulevard, Frisco, TX 75034.	March 21, 2016	480134
Comal (FEMA Docket No.: B–1600).	City of New Braunfels (15-06-4062P).	The Honorable Barron Casteel, Mayor, City of New Braunfels, 424 South Castell Avenue, New Braunfels, TX 78130.	Building Division, 424 South Castell Avenue, New Braunfels, TX 78130.	March 31, 2016	485493
El Paso (FEMA Docket No.: B–1600).	City of El Paso (15-06-3494P)	The Honorable Oscar Leeser, Mayor, City of El Paso, 300 North Campbell Street, El Paso, TX 79901.	Land Development Department, 801 Texas Avenue, El Paso, TX 79901.	April 14, 2016 ..	480214
Grimes (FEMA Docket No.: B–1600).	Unincorporated areas of Grimes County (15-06-3274P).	The Honorable Ben Leman, Grimes County Judge, P.O. Box 160, Anderson, TX 77830.	Grimes County Road and Bridge Engineering Department, 1010 Highway 90 South, Anderson, TX 77830.	April 14, 2016 ..	481173
Rockwall (FEMA Docket No.: B–1600).	City of Rockwall (15-06-0488P)	The Honorable Jim Pruitt, Mayor, City of Rockwall, 385 South Goliad Street, Rockwall, TX 75087.	City Hall, 385 South Goliad Street, Rockwall, TX 75087.	March 28, 2016	480547
Travis (FEMA Docket No.: B–1600).	City of Manor (15-06-2824P)	The Honorable Rita G. Jonse, Mayor, City of Manor, P.O. Box 387, Manor, TX 78653.	City Hall, 201 East Parsons Street, Manor, TX 78653.	April 11, 2016 ..	481027
Travis (FEMA Docket No.: B–1600).	Unincorporated areas of Travis County (15-06-2824P).	The Honorable Sarah Eckhardt, Travis County Judge, P.O. Box 1748, Austin, TX 78767.	Travis County Office of Emergency Management, 5010 Old Manor Road, Austin, TX 78723.	April 11, 2016 ..	481026
Williamson (FEMA Docket No.: B–1605).	City of Cedar Park (15–06–3037P)	The Honorable Matthew Powell, Mayor, City of Cedar Park, 450 Cypress Creek Road, Cedar Park, TX 78613.	Public Works Department, 2401 Brushy Creek Loop, Cedar Park, TX 78613.	March 31, 2016	481282
Williamson (FEMA Docket No.: B–1605).	Unincorporated areas of Williamson County (15–06–3037P).	The Honorable Dan A. Gattis, Williamson County Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626.	Williamson County Engineer's Office, 3151 Southeast Inner Loop, Suite B, Georgetown, TX 78626.	March 31, 2016	481079
Virginia:					
Fairfax (FEMA Docket No.: B–1600).	Unincorporated areas of Fairfax County (15-03-1692P).	The Honorable Edward L. Long, Jr., Fairfax County Executive, 12000 Government Center Parkway, Fairfax, VA 22035.	Fairfax County Stormwater Planning Division, 12000 Government Center Parkway, Fairfax, VA 22035.	March 29, 2016	515525

[FR Doc. 2016–15755 Filed 7–1–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4259–DR; Docket ID FEMA–2016–0001]

Georgia; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Georgia (FEMA–4259–DR), dated February 26, 2016, and related determinations.

DATES: *Effective Date:* May 26, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Warren J. Riley, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Rosalyn L. Cole as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15813 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4269–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4269–DR), dated April 25, 2016, and related determinations.

DATES: *Effective Date:* June 3, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the Public Assistance program for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 25, 2016.

Bastrop, Bosque, Callahan, Coryell, Milam, and Washington Counties for Public Assistance.

Austin, Colorado, Fayette, Grimes, Harris, Montgomery, San Jacinto, Waller, and Wharton Counties for Public Assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15752 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0014; OMB No. 1660–0033]

Agency Information Collection Activities: Proposed Collection; Comment Request; Residential Basement Floodproofing Certification

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the certification of floodproofed residential basements in Special Flood Hazard Areas (SFHAs).

DATES: Comments must be submitted on or before September 6, 2016.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2016–0014. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mary Chang, Insurance Examiner, FEMA, Mitigation Directorate, (202) 212–4712 for additional information. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency

(FEMA) is authorized to establish and carry out a National Flood Insurance Program (NFIP) to enable interested persons to purchase insurance against flood loss. *See,* 42 U.S.C. 4001 *et seq.* Flood insurance under the NFIP can be sold or renewed only within a community that has adopted adequate floodplain management regulations consistent with the Federal criteria in the NFIP regulations. *See,* 44 CFR 60.3. FEMA's minimum floodplain management criteria require that all new construction and substantial improvements of residential structures within Zones A1–30, AE and AH have the lowest floor, including the basement, elevated at or above the base flood level. FEMA can grant an exception to this rule after a community submits a proposal to FEMA to adopt standards for floodproofing residential basements below the base flood level in zones A1–30, AH, AO, and AE in accordance with 44 CFR 60.6(c). When FEMA grants an exception to a community under 44 CFR 60.6(c), property owners in these communities submit a Residential Basement Floodproofing Certificate with their NFIP application for flood insurance for rating purposes. The certification also provides community officials with information to determine compliance with the community's floodplain management ordinance.

Collection of Information

Title: Residential Basement Floodproofing Certification.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0033.

FEMA Forms: FEMA Form 086–0–24, Residential Basement Floodproofing Certificate.

Abstract: The Residential Basement Floodproofing Certification is completed by an engineer or architect and certifies that the basement floodproofing meets the minimum floodproofing specifications of FEMA. This certification is for residential structures located in non-coastal Special Flood Hazard Areas in communities that have received an exception to the requirement that structures be built at or above the Base Flood Elevation (BFE) under 44 CFR 60.6(c). Residential structures with certification showing the building is floodproofed to at least 1 foot above the BFE are eligible for lower rates on flood insurance.

Affected Public: Individuals or households, Business or other for-profit.

Number of Respondents: 100.

Number of Responses: 100.

Estimated Total Annual Burden Hours: 325 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $18,151. The annual costs to respondents' operations and maintenance costs for technical services is $35,000. There are no annual start-up or capital costs. The cost to the Federal Government is $2,885.71.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Dated: June 29, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–15825 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–52–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1626]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Date: May 19, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Idaho: Ada	Unincorporated areas of Ada County (16–10–0446P).	Mr. Jim Tibbs, Chairman, Board of County Commissioners, 200 West Front Street, 3rd Floor, Boise, ID 83702.	Ada County Courthouse, 200 West Front Street, Boise, ID 83702.	*http://www.msc.fema.gov/lomc*	August 9, 2016	160001
Indiana: Hendricks	Unincorporated areas of Hendricks County (16–05–2570P).	Mr. Michael E. Graham, Administrator to the County Commissioner, Hendricks County Government Center, 355 South Washington Street, Danville, IN 46122.	Hendricks County Government Center, 355 South Washington Street, Danville, IN 46122.	*http://www.msc.fema.gov/lomc*	July 7, 2016	180415
New Jersey:.						
Burlington	Township of Medford (16–02–0032P).	The Honorable Jeffrey Beenstock, Mayor, Township of Medford, 17 North Main Street, Medford, NJ 08055.	Municipal Center, 17 North Main Street, Medford, NJ 08055.	*http://www.msc.fema.gov/lomc*	August 5, 2016	340104
Middlesex	Borough of Middlesex (16–02–0324P).	The Honorable Ronald J. DiMura, Mayor, Borough of Middlesex, 1200 Mountain Avenue, Middlesex, NJ 08846.	Municipal Court, 1200 Mountain Avenue, Middlesex, NJ 08846.	*http://www.msc.fema.gov/lomc*	July 18, 2016	345305
Somerset	Borough of Bound Brook (16–02–0324P).	The Honorable Robert Fazen, Mayor, Borough of Bound Brook, 230 Hamilton Street, Bound Brook, NJ 08805.	Municipal Building, 230 Hamilton Street, Bound Brook, NJ 08805.	*http://www.msc.fema.gov/lomc*	July 18, 2016	340430
Somerset	Borough of South Bound Brook (16–02–0324P).	The Honorable Caryl Shoffner, Mayor, Borough of South Bound Brook, 12 Main Street, South Bound Brook, NJ 08880.	Municipal Building, 12 Main Street, South Bound Brook, NJ 08880.	*http://www.msc.fema.gov/lomc*	July 18, 2016	340445
Somerset	Township of Bridgewater (16–02–0324P).	The Honorable Daniel J. Hayes, Jr., Mayor, Township of Bridgewater, 100 Commons Way, Bridgewater, NJ 08807.	Department of Code Enforcement, 700 Garretson Road, Bridgewater, NJ 08807.	*http://www.msc.fema.gov/lomc*	July 18, 2016	340432
Somerset	Township of Bridgewater (16–02–0607P).	The Honorable Daniel J. Hayes, Jr., Mayor, Township of Bridgewater, 100 Commons Way, Bridgewater, NJ 08807.	Township of Bridgewater, Department of Code Enforcement, 700 Garretson Road, Bridgewater, NJ 08807.	*http://www.msc.fema.gov/lomc*	August 4, 2016	340432
New York: Cortland	Town of Scott (16–02–0318P).	Mr. Kevin Fitch, Town Supervisor, Town of Scott, Town Hall, 6689 NYS Route 41, Homer, NY 13077.	Town Hall, 6689 NYS Route 41, Homer, NY 13077.	*http://www.msc.fema.gov/lomc*	August 12, 2016	361328

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Ohio: Licking	Village of Granville (16–05–1572P).	The Honorable Melissa Hartfield, Mayor, Village of Granville, City Hall, 141 East Broadway Street, Granville, OH 43023.	Village Offices, 141 East Broadway Street, Granville, OH 43023.	*http://www.msc.fema.gov/lomc*	August 4, 2016 ..	390330
Oregon:						
Multnomah	City of Portland (16–10–0674P).	The Honorable Charlie Hales, Mayor, City of Portland, 1221 Southwest 4th Avenue, Room 340, Portland, OR 97204.	Bureau of Environmental Services, 1221 Southwest 4th Avenue, Room 230, Portland, OR 97204.	*http://www.msc.fema.gov/lomc*	August 12, 2016	410183
Washington	City of Beaverton (15–10–1269P).	The Honorable Denny Doyle, Mayor, City of Beaverton, The Beaverton Building, 12725 Southwest Millikan Way, Beaverton, OR 97005.	City Hall, Planning & Engineering Department, 12725 Southwest Millikan Way, Beaverton, OR 97005.	*http://www.msc.fema.gov/lomc*	August 19, 2016	410240
Wisconsin: Waukesha.	City of Brookfield (16–05–2092P).	The Honorable Steven V. Ponto, Mayor, City of Brookfield, 2000 North Calhoun Road, Brookfield, WI 53005.	City Hall, 2000 North Calhoun Road, Brookfield, WI 53005.	*http://www.msc.fema.gov/lomc*	August 12, 2016	550478

[FR Doc. 2016–15751 Filed 7–1–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4272–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4272–DR), dated June 11, 2016, and related determinations.

DATES: Effective June 22, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 11, 2016.

Bastrop, Burleson, Eastland, Lee, Liberty, Stephens, and Tyler Counties for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15746 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4266–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Texas (FEMA–4266–DR), dated March 19, 2016, and related determinations.

DATES: *Effective Date:* May 23, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Kevin L. Hannes as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15811 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4273–DR; Docket ID FEMA–2016–0001]

West Virginia; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of West Virginia (FEMA–4273–DR), dated June 25, 2016, and related determinations.

DATES: *Effective Date:* June 25, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 25, 2016, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

> I have determined that the damage in certain areas of the State of West Virginia resulting from severe storms, flooding, landslides, and mudslides beginning on June 22, 2016, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of West Virginia.
>
> In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.
>
> You are authorized to provide Individual Assistance and assistance for emergency protective measures (Category B) under the Public Assistance program in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate subject to completion of Preliminary Damage Assessments (PDAs). Direct Federal assistance is authorized.
>
> Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.
>
> Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Albert Lewis, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of West Virginia have been designated as adversely affected by this major disaster:

Greenbrier, Kanawha, and Nicholas Counties for Individual Assistance.

Greenbrier, Kanawha, and Nicholas Counties for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

All areas within the State of West Virginia are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15824 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4245–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Texas (FEMA–4245–DR), dated November 25, 2015, and related determinations.

DATES: *Effective Date:* May 23, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Kevin L. Hannes as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15810 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4223–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 13 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Texas (FEMA–4223–DR), dated May 29, 2015, and related determinations.

DATES: *Effective Date:* May 23, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Kevin L. Hannes as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15821 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4255–DR; Docket ID FEMA–2016–0001]

Texas; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for State of Texas (FEMA–4255–DR), dated February 9, 2016, and related determinations.

DATES: *Effective Date:* May 23, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Kevin L. Hannes as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15814 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4272–DR; Docket ID FEMA–2016–0001

Texas; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Texas (FEMA–4272–DR), dated June 11, 2016, and related determinations.

DATES: *Effective Date:* June 11, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 11, 2016, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

> I have determined that the damage in certain areas of the State of Texas resulting from severe storms and flooding beginning on May 26, 2016, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Texas.
>
> In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.
>
> You are authorized to provide Individual Assistance and assistance for emergency protective measures (Category B) under the Public Assistance program in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate subject to completion of Preliminary Damage Assessments (PDAs). Direct Federal assistance is authorized.
>
> Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal

implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Texas have been designated as adversely affected by this major disaster:

Austin, Brazoria, Brazos, Fort Bend, Grimes, Hidalgo, Hood, Montgomery, San Jacinto, Travis, Waller, and Washington Counties for Individual Assistance.

Austin, Brazoria, Brazos, Fort Bend, Grimes, Hidalgo, Hood, Montgomery, San Jacinto, Travis, Waller, and Washington Counties for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

All areas within the State of Texas are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–15753 Filed 7–1–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1627]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before October 3, 2016.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1627, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: May 19, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Non-watershed-based studies:

Community	Community map repository address
Sacramento County, California, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–09–2391S Preliminary Date: February 26, 2016	
Unincorporated Areas of Sacramento County	Municipal Services Agency, Department of Water Resources, 827 7th Street, Suite 301, Sacramento, CA 95814.
Wright County, Minnesota, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 08–05–4043S Preliminary Date: June 22, 2011	
City of Buffalo	Administration Office, 212 Central Avenue, Buffalo, MN 55313.
City of Clearwater	City Hall, 605 County Road 75, Clearwater, MN 55320.
City of Cokato	City Clerk Office, 255 Broadway Avenue South, Cokato, MN 55321.
City of Delano	City Hall, 234 North 2nd Street, Delano, MN 55328.
City of Maple Lake	City Hall, 10 Maple Avenue South, Maple Lake, MN 55358.
City of Monticello	City Hall, 505 Walnut Street, Suite One, Monticello, MN 55362.
City of Montrose	City Hall, 311 Buffalo Avenue South, Montrose, MN 55363.
City of Otsego	City Hall, 13400 90th Street Northeast, Otsego, MN 55330.
City of St. Michael	City Hall, 11800 Town Center Drive Northeast, St. Michael, MN 55376.
City of Waverly	City Hall, 502 Atlantic Avenue, Waverly, MN 55390.
Unincorporated Areas of Wright County	Wright County Government Center, 10 2nd Street Northwest, Buffalo, MN 55313.
Muskingum County, Ohio, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–05–2523S Preliminary Date: September 18, 2015	
Unincorporated Areas of Muskingum County	Mapping Department, 401 Main Street, Zanesville, OH 43701.
Village of Roseville	Municipal Building, 107 North Main Street, Roseville, OH 43777.
Perry County, Ohio, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–05–2523S Preliminary Date: September 18, 2015	
Unincorporated Areas of Perry County	County Offices, 109–A East Gay Street, Somerset, OH 43783.

[FR Doc. 2016–15767 Filed 7–1–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR- 5921–N–08]

Privacy Act of 1974; Notice of a Computer Matching Program Between the Department of Housing and Urban Development (HUD) and the Department of Justice (DOJ)

AGENCY: Office of Administration, HUD.

ACTION: Notice of a Computer Matching Program between HUD and DOJ.

SUMMARY: In accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Public Law 100–503), and the Office of Management and Budget (OMB) Guidelines on the Conduct of Matching Programs (54 FR 25818 (June 19, 1989); and OMB Bulletin 89–22, "Instructions on Reporting Computer Matching Programs to the Office of Management and Budget (OMB), Congress and the Public," HUD is issuing a public notice of its intent to conduct a recurring computer matching program with DOJ for the purpose of incorporating DOJ debtor files into the Credit Alert Verification Reporting System (CAIVRS), which is a HUD computer information system.

DATES: *Effective Date:* The effective date of the matching program shall begin August 4, 2016, or at least 40 days from the date that copies of the Computer Matching Agreement, signed by both HUD and DOJ Data Integrity Boards (DIBs), are sent to OMB and Congress, whichever is later, provided that no comments that would result in a contrary determination are received.

Comments Due Date: August 4, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10110, Washington, DC 20410. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Contact the "Recipient Agency" Frieda B. Edwards, Acting Departmental Privacy Officer, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number (202) 402–6828 or the "Source Agency" Diane E. Watson, Debt Collection Management, Nationwide Central Intake facility (NCIF), Department of Justice, 45 N Street NE., Washington, DC 20530, telephone number (301) 582–4353. [These are not toll-free numbers.] A telecommunication device for hearing- and speech-impaired individuals (TTY) is available at (800) 877–8339 (Federal Relay Service).

SUPPLEMENTARY INFORMATION: HUD's CAIVRS database includes delinquent debt information from the Departments of Education (ED), Veteran's Affairs (VA), the Small Business Administration (SBA), and the U.S. Department of Agriculture (USDA). This data match will allow the prescreening of applicants for federal direct loans or federally guaranteed loans, for the purpose of determining the applicant's credit worthiness, by ascertaining whether the applicant is delinquent or in default on a loan owed directly to, or Federally guaranteed by, the Federal government. Lending Federal agencies and authorized private lending institution will be able to use the CAIVRS debtor file to verify that the loan applicant is not in default, or delinquent on a Federal direct or Federally guaranteed loan, prior to granting the applicant a loan. The CAIVRS database contains Personally Identifiable Information (PII) contributed by participating Federal agencies, including Social Security Numbers (SSNs) and other records of borrowers delinquent or in default on debts owed to, or guaranteed by HUD and other Federal agencies. Authorized users may not deny, terminate, or make a final decision concerning any loan assistance to an applicant or take other adverse action against such applicant based on the information produced by data matches conducted under CAIVRS, until such authorized users have independently verified such adverse information.

Reporting of Matching Program

In accordance with Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988 as amended, and OMB Bulletin 89–22, "Instructions on Reporting Computer Matching Programs to the Office of Management and Budget (OMB), Congress and the Public," copies of this notice and report are being provided to the U.S. House Committee on Oversight Government Reform, the U.S. Senate Homeland Security and Governmental Affairs Committee, and OMB.

Authority

HUD has authority to collect and review mortgage data pursuant to the National Housing Act, as amended, 12 U.S.C. 1701 *et seq.*, and related laws. This computer matching will be conducted pursuant to Public Law 100–503, "The Computer Matching and Privacy Protection Act of 1988," as amended, and OMB Circulars A–129 (Managing Federal Credit Programs). One of the purposes of all Executive departments and agencies is to implement efficient management practices for Federal Credit Programs. OMB Circular A–129 was issued under the authority of the Budget and Accounting Act of 1921, as amended; the Budget and Accounting Act of 1950, as amended; the Debt Collection Act of 1982, as amended by the Debt Collection Improvement Act of 1996; section 2653 of Public Law 98–369; the Federal Credit Reform Act of 1990, as amended; the Federal Debt Collection Procedures Act of 1990, the Chief Financial Officers Act of 1990, as amended; Executive Order 8248; the Cash Management Improvement Act Amendments of 1992; and pre-existing common law authority to charge interest on debts and to offset payments to collect debts administratively.

Objectives To Be Met by the Matching Program

The objective of this matching program is to give program agencies access to a system that allows them to prescreen applicants for loans made, or loans guaranteed, by the Federal Government to ascertain if the applicant is delinquent in paying a debt owed to or guaranteed by the Federal Government. As part of this process, HUD will be provided access to DOJ's debtor data for prescreening purposes.

The use of CAIVRS will allow HUD to better monitor its credit programs and to reduce the credit extended to individuals with outstanding delinquencies on debts owed to HUD and other Federal agencies. DOJ expects that its participation in CAIVRS will further other Federal agencies' efforts to reduce credit risks through loan prescreening, and prompt student loan defaulters, who are denied credit by other Federal agencies, to make arrangements to repay their defaulted student loans.

Under this computer matching program, HUD/CAIVRS receives limited information on borrowers who have defaulted on loans administered by participating Federal agencies each month. The information includes: Borrower ID Number—The Social Security Number (SSN), Employer Identification Number (EIN) or Taxpayer Identification Number (TIN) of the borrower on a delinquent or defaulted Federal direct loan or Federally guaranteed loan. Federal agency personnel and authorized lenders must enter a user authorization code followed by either a SSN or EIN to access CAIVRS. Only the following information is returned or displayed:

- Yes/No as to whether the holder of that SSN/EIN is in default on a Federal loan; and
- If Yes, then CAIVRS provides to the lender:
    - Loan case number;
    - Record type (claim, default, foreclosure, or judgment);
    - Agency administering the loan program;
    - Phone number at the applicable Federal agency (to call to clear up the default); and
    - Confirmation Code associated with the query.

Federal law mandates the suspension of the processing of applications for Federal credit benefits (such as government-insured loans) if the applicants are delinquent on Federal or Federally guaranteed debt. Processing may continue only after the borrower satisfactorily resolves the debt (*e.g.,* pays in full or renegotiates a new payment plan). To remove a CAIVRS sanction, the borrower must contact the Federal agency that reported their SSN or EIN to HUD/CAIVRS using the information provided.

Records To Be Matched

HUD will use records from the Single Family Default Monitoring System (SFDMS/F42D (72 FR 65350 November 20, 2007)), and Single Family Insurance

System—Claims Subsystem (CLAIMS/A43C (72 FR 65348 November 20, 2007)), as combined in CAIVRS to provide an up-to-date dataset to be used in records matching. SFDMS maintains data on mortgages that are 90 or more days delinquent. The Mortgagee or Servicer must submit a Monthly Delinquent Loan Report (HUD–92068–A) to HUD on a monthly basis until the mortgage status has been completed by all Mortgagees, or is otherwise terminated or deleted. Mortgagees and Servicers provide default data to HUD via Electronic Data Interchange (EDI) or using the Internet via FHA Connection, through which the data is sorted, pre-screened, key entered, edited, and otherwise processed. Reports are generated for HUD Headquarters and Field Offices to review.

CLAIMS provides automated receipt, tracking and processing of form HUD–27011, Single Family Application for Insurance Benefits. CLAIMS provides online update and inquiry capability to Single Family Insurance and Claims databases, and to cumulative history files. Claim payments are made by Electronic Funds Transfer (EFT) via an HDS platform (IBM mainframe/Treasury interface) on a daily basis.

The DOJ will provide HUD with debtor files. These files are maintained in a Department wide DOJ system of records entitled, Debt Collection Enforcement System, JUSTICE/DOJ–016. The notice for this system of records, including a routine use permitting this disclosure, was published in the **Federal Register** on February 21, 2012 (77 FR 9965–9968). The DOJ debtor files contain information on individuals or corporations with unsatisfied judgments.

Notice Procedures

HUD will notify individuals at the time of application for a HUD/FHA mortgage. HUD and DOJ published a notice concerning routine use disclosures in the **Federal Register** to inform individuals that a computer match may be performed to determine a loan applicant's credit status with the Federal Government. The Privacy Act also requires that a copy of each Computer Matching Agreement entered into with a recipient agency shall be available upon request to the public.

Categories of Records/Individuals Involved

Data elements disclosed in computer matching governed by this Agreement are Personally Identifiable Information (PII) from the specified DOJ system of record. The data elements supplied by DOJ to CAIVRS are the following:

- Borrower ID Number—The Social Security Number (SSN), Employer Identification
- Number (EIN) or Taxpayer Identification Number (TIN) of the borrower on a delinquent or defaulted Federal direct loan or federally guaranteed loan.
- Case Number—A reference number issued by the reporting agency for the delinquent or defaulted federal direct loan or federally guaranteed loan.
- Agency Code—A code assigned to the reporting agency.
- Type Code—A code that indicates the type of record—claim, default, foreclosure, or judgment.
- Borrower ID Type—A code that indicates whether the Borrower ID Number is a SSN, EIN, or TIN.

Period of the Match

Matching will begin at least 40 days from the date that copies of the Computer Matching Agreement, signed by HUD and DOJ DIBs, are sent to both Houses of Congress and OMB; or at least 30 days from the date this notice is published in the **Federal Register**, whichever is later, provided that no comments that would result in a contrary determination are received. The matching program will be in effect and continue for 18 months with an option to renew for 12 additional months unless one of the Parties to the Agreement advises the other in writing to terminate or modify the Agreement.

Dated: June 17, 2016.

Patricia A. Hoban-Moore,

Chief Administrative Officer.

[FR Doc. 2016–15863 Filed 7–1–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[15XL LLIDB00100 LF1000000.HT0000 LXSS020D0000 241A 4500076900]

Final Supplementary Rules for the Cove Recreation Site, Owyhee County, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Final supplementary rules.

SUMMARY: The Bureau of Land Management (BLM) is finalizing supplementary rules for public use of the campground and day use areas at Cove Recreation Site, located along C.J. Strike Reservoir in the Morley Nelson Snake River Birds of Prey National Conservation Area (NCA) in Owyhee County, Idaho. These final supplementary rules are compatible and consistent with the September 2008 Record of Decision (ROD) for the NCA's resource management plan (RMP).

DATES: These final supplementary rules are effective August 4, 2016.

ADDRESSES: You may direct your inquiries to the Bureau of Land Management, Four Rivers Field Office, 3948 S. Development Avenue, Boise, ID 83705. Electronic mail: *blm_id_cove_rec_rules@blm.gov*.

FOR FURTHER INFORMATION CONTACT: Jared Fluckiger, Outdoor Recreation Planner, Bureau of Land Management, Four Rivers Field Office, 3948 S. Development Avenue, Boise, ID 83705, telephone 208–384–3342. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours (8:00 a.m.–4:30 p.m.). You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

I. Background

The Cove Recreation Site is a 29-unit campground and day-use site located along C.J. Strike Reservoir, about 35 miles southwest of Mountain Home in southwestern Idaho. The site provides opportunities to fish, hike, view wildlife, boat (motorized and non-motorized), waterski, swim, camp, and picnic.

There are no changes to Cove Recreation Site user fees, which were established in 2005 under the Federal Lands Recreation Enhancement Act. The final supplementary rules will help the BLM achieve management objectives for the Snake River Birds of Prey NCA, which include restoring and rehabilitating non-shrub areas, and improving raptor and raptor prey habitat, while imposing only moderate restrictions on recreation. They will also provide the BLM with the enforcement tools needed to enhance public health and safety and help prevent damage to natural and cultural resources.

II. Discussion of Public Comments

The BLM published proposed supplementary rules for the Cove Recreation Site in the **Federal Register** on June 25, 2014 (79 FR 36094). Originally, public comments were due August 25, 2014. The BLM accepted comments from the Owyhee County Commission on September 15, 2014, at the next in a series of monthly coordination meetings held to facilitate communication and understanding of BLM issues and decisions of concern to the County. The Commission had notified the BLM in a letter dated August 18, 2014, that it would need additional time beyond the original due date for comments to respond. Had the BLM received other comments in the period between August 25, 2014, and September 15, 2014, those comments would also have been accepted. However, no comments besides those from the Owyhee County Commission on September 15, 2014, were received after August 25, 2014.

The Owyhee County Commission's comments showed support for increasing the proposed number of people allowed per site by 2 for single, double, and triple sites. In response to these comments, in the final rule the maximum number of people per campsite was changed to 8 for a single site, 12 for a double site, and 16 for a triple site.

During the regular comment period, the BLM received one form letter sent or signed by 121 people. The letter identified three concerns. The first concern was that camping would no longer be permitted on undeveloped land to the west of the developed portion of Cove Recreation Site fee area. This area was included in the 160 acres analyzed by the 2003 environmental assessment (EA), but is currently outside the fee area that contains developed recreation sites and facilities.

The second concern was that restricting the number of people per campsite to 6 for a single site would burden larger and/or low-income families.

The third concern was that the rule that does not permit off-highway vehicle (OHV) use within the campground would be applied outside the developed portion of the campground to the west.

In response to these comments, the final supplementary rules clarify that they only apply to the area within the developed recreation site, RV dump, and related facilities. The boundaries include a fence line one-half mile east from the boat ramp at Black Sands, the Cove Inlet on the east side of the recreation site and, the BLM private property lines on the south side. These rules will be applied within these boundaries.

Rule number four, which restricts the number of people per campsite, was changed in the final rule to 8 for a single site, 12 for a double site, and 16 for a triple site.

III. Discussion of the Final Supplementary Rules

These final supplementary rules will help the BLM achieve management objectives for the NCA and implement the decision associated with the 2003 environmental assessment (EA) for Reconstruction of the Cove Recreation Site, C.J. Strike Reservoir, 2003 EA No. ID 090 03 022 (2003 EA). These final supplementary rules are compatible and consistent with the ROD for the NCA's RMP. The final supplementary rules also provide the BLM with the enforcement tools needed to help prevent damage to natural and cultural resources and provide for public health and safety.

These final supplementary rules revise some of the definitions that were in the proposed supplementary rules. The definition of "Motorbike" is revised to correct a typographical error ("trials bikes" has been changed to "trail bikes"). The definition of "Specialty off-highway vehicle" is revised to clarify that a mention of other definitions refers to other definitions that are found in these supplementary rules. The definition of "Utility type vehicle" is revised to delete a reference to a definition of "snowmobile," which does not appear in these supplementary rules.

Rule number one requires immediate payment of user fees at a self-service pay station. It also provides that holders of Golden Age or Golden Access Passports are entitled to a 50 percent fee reduction. Acting on a recommendation from the BLM's law enforcement officers, rule number one has been revised. As proposed, the first sentence in rule number one would have stated, "User fees must be paid within one hour of arrival to the campground for overnight use and must be paid immediately upon arrival for day use." That sentence in the final supplementary rule states, "User fees must be paid immediately upon parking or entering Cove Recreation Site." This change will help ensure prompt payment of user fees.

Rule number two provides that fees for overnight camping permit up to two vehicles per numbered campsite, and requires an extra fee for additional vehicles.

Rule number three permits camping only at numbered sites and rule number four limits the number of visitors allowed in each site. These rules will help ensure public safety and protect resources.

Rule number five requires a check-out time of 2:00 p.m. to allow other users to use a site.

Rule number six will prevent resource damage by prohibiting cross-country vehicle travel within the campground.

Rule number seven prohibits the use of OHVs in the campground. This rule will help ensure the protection of persons, property, and resources.

Rule number eight prohibits vehicles and camping gear from being left unattended in the recreation site for longer than 24 hours. This rule will assist in making the recreation site available to other visitors.

Rule number nine establishes quiet hours so that visitors may rest and sleep without interruption.

Rule numbers ten and eleven establish acceptable behavior regarding the use of campfires and obtaining campfire fuel. These rules will help ensure visitor safety and will help prevent resource damage.

Rule number twelve requires immediate removal and disposal of refuse. This rule will help ensure visitor safety and prevent resource damage. The second sentence of rule number twelve is revised in response to a recommendation from the BLM's law enforcement officers. As proposed, that sentence would have stated, "All persons must keep their sites free of trash and litter during the period of occupancy." The second sentence of the final supplementary rule states, "All persons must keep and leave their sites free of trash and litter at all times." The BLM believes that compared to the proposed wording, this wording will more effectively ensure public safety.

Rule number thirteen prohibits dumping of graywater or blackwater anywhere outside an approved area. This rule will help safeguard public safety.

Rule number fourteen provides that the maximum length of stay in the campground is 14 consecutive days. This rule will prevent semi-permanent visitation.

Rule number fifteen prohibits the use or discharge of paintball equipment in the campground and day-use areas. This rule will help reduce conflict between users of the established recreation area and potential damage to facilities.

The BLM has replaced the proposed "Penalties" provision. The replacement, titled "Enforcement," improves the precision and accuracy of the supplementary rules.

IV. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

The final supplementary rules are not a significant regulatory action and are not subject to review by the Office of

Management and Budget under Executive Order 12866. They will not have an effect of $100 million or more on the economy. They will not adversely affect, in a material way, the economy; productivity; competition; jobs; environment; public health or safety; or State, local or tribal governments or communities. The final supplementary rules will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. They do not materially alter the budgetary effects of entitlements, grants, or loan programs or the right or obligations of their recipients; nor do they raise novel legal or policy issues. The final supplemental rules impose rules of conduct for public use of a limited selection of public lands and provide greater consistency with the Idaho State Code to protect public health and safety.

National Environmental Policy Act (NEPA)

The BLM prepared the 2003 EA to evaluate the environmental effects of the reconstruction of the Cove Recreation Site. These final supplementary rules are designed to mitigate issues discussed in the 2003 EA. This action is strictly procedural and is therefore categorically excluded pursuant to 516 DM 2, Appendix 1.10. There are no extraordinary circumstances that would present potentially significant effects to the environment.

The BLM has noted an increasing network of trails throughout the NCA due to widespread OHV use throughout the area. The 2003 EA states that the ground surrounding the structures on the site is disturbed and highly compacted from historic and heavy unrestricted vehicle traffic. As a result, soil erosion is a concern at the Cove Recreation Site, particularly on the east side of the inlet. The associated impacts to vegetation, water quality, and public health are also a concern. Uncontrolled OHV activity impacts wildlife populations (including raptors) and their habitats, and can adversely impact other recreational uses. The final supplementary rules are designed to mitigate:

1. OHV impacts to wildlife, soils, and vegetation;
2. User conflicts (noise, pets, weapons, vehicle speeding, etc.); and
3. Human-caused wildfires.

OHV impacts and user conflicts are described in the decision record for the 2003 EA, which is available for review in the BLM administrative record at the address specified in the **ADDRESSES** section.

The impacts from human-caused wildfires are described in the ROD for the 2008 Snake River Birds of Prey National Conservation Area RMP EIS. The ROD for the RMP EIS was signed by the BLM Idaho State Director on September 30, 2008. The ROD is available for review in the BLM administrative record at the address specified in the **ADDRESSES** section and online at: *https://www.blm.gov/epl-front-office/eplanning/planAndProjectSite.do?methodName=dispatchToPatternPage&currentPageId=46154.*

The issues that form the basis of these final supplementary rules were analyzed in the 2003 EA for reconstruction of the site. The final supplementary rules are also compatible and consistent with the 2008 ROD for the NCA's RMP and also provide for enforcement.

The BLM found that the final supplementary rules would not constitute a major Federal action significantly affecting the quality of the human environment under NEPA section 102(2)(C), 42 U.S.C. 4332(2)(C).

Regulatory Flexibility Act of 1980

Congress enacted the Regulatory Flexibility Act of 1980 (RFA), as amended, 5 U.S.C. 601–612, to ensure Government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. These final supplementary rules establish rules of conduct for public use of a limited area of public lands and should have no effect on business entities of any size. Therefore, the BLM has determined, under the RFA, that they would have no significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

These final supplementary rules establish rules of conduct for public use of a limited area of public lands and do not affect commercial or business activities of any kind. Thus, the rules do not constitute a "major rule" as defined at 5 U.S.C. 804(2). They will not result in an effect on the economy of $100 million or more, an increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

These final supplementary rules will not impose an unfunded mandate on State, local or tribal governments in the aggregate or the private sector of more than $100 million per year, nor will they have a significant or unique effect on State, local, or tribal governments or the private sector. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

These final supplementary rules will not have significant takings implications, nor will they be capable of interfering with constitutionally protected property rights, as no property rights are at stake in this final rule. Therefore, the BLM has determined these rules will not cause a "taking" of private property or require preparation of a takings assessment.

Executive Order 13132, Federalism

The final supplementary rules do not have a substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. The final supplementary rules will not conflict with any Idaho state law or regulation, but provide greater consistency with the Idaho State Code to protect public health and safety. Therefore, in accordance with Executive Order 13132, the BLM has determined these final supplementary rules will not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

The BLM has determined these final supplementary rules will not unduly burden the judicial system and they meet the requirements of sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

The Shoshone-Bannock Tribes of the Fort Hall Indian Reservation and Shoshone-Paiute Tribes of the Duck Valley Indian Reservation were consulted during planning for the environmental assessment for reconstruction of the site and supported these decisions. The tribes continue to be consulted regularly on implementation actions. Based on these consultations, the BLM has determined that these supplementary rules do not involve policies having tribal implications.

Executive Order 13352, Facilitation of Cooperative Conservation

In accordance with Executive Order 13352, the BLM has determined that the final supplementary rules will not impede facilitating cooperative conservation; will take appropriate account of and consider the interests of persons with ownership or other legally recognized interests in land or other natural resources; will properly accommodate local participation in the Federal decision-making process; and will provide that the programs, projects, and activities are consistent with protecting public health and safety.

Information Quality Act

The Information Quality Act (Section 515 of Pub. L. 106–554) requires Federal agencies to maintain adequate quality, objectivity, utility, and integrity of the information they disseminate. In developing these supplementary rules, the BLM did not conduct or use a study, experiment, or survey, or disseminate any information to the public.

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

These final supplementary rules will not constitute a significant energy action. The final supplementary rules will not have an adverse effect on energy supplies, production, or consumption, and have no connection with energy policy.

Paperwork Reduction Act

These final supplementary rules do not contain information collection requirements that the Office of Management and Budget must approve under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

AUTHOR: The principal author of these supplementary rules is Jared Fluckiger, NCA Outdoor Recreation Planner.

For the reasons stated in the preamble, and under the authority of 43 CFR 8365.1–6, the BLM establishes final supplementary rules for BLM-managed public lands at the Cove Recreation Site, to read as follows:

FINAL SUPPLEMENTARY RULES FOR THE COVE RECREATION SITE

Definitions

Blackwater means water that contains animal, human, or food waste.

Graywater means wastewater drained from sinks, tubs, showers, dishwashers, clothes washers, and other non-toilet sources.

Off-highway vehicle (OHV) For the purpose of these supplementary rules, the following are included within the definition of OHV (taken from Idaho Code 67–7101 (2010)):

- "All-terrain vehicle" or "ATV" means any recreation vehicle that has 3 or more tires and measures 50 inches or less in width, having a wheelbase of 61 inches or less, having handlebar steering and a seat designed to be straddled by the operator.
- "Motorbike" means any self-propelled two-wheeled motorcycle or motor-driven cycle, excluding tractors, designed for or capable of traveling off developed roadways and highways and also referred to as trailbikes, enduro bikes, trail bikes, motocross bikes, or dual purpose motorcycles.
- "Specialty off-highway vehicle" means any vehicle manufactured, designed or constructed exclusively for off-highway operation that does not fit the definition of an all-terrain vehicle, utility type vehicle, or motorbike as defined in these supplementary rules.
- "Utility type vehicle" or "UTV" means any recreational motor vehicle other than a snowmobile or an ATV or motorbike as defined in this section, designed for and capable of travel over designated roads, traveling on 4 or more tires, maximum width less than 74 inches, maximum weight less than 2,000 pounds, and having a wheelbase of 110 inches or less. A utility type vehicle must have a minimum width of 50 inches, a minimum weight of at least 900 pounds or a wheelbase of over 61 inches. This does not include golf carts, vehicles specially designed to carry a disabled person, or implements of husbandry. A "utility type vehicle" or "UTV" also means a recreational OHV, or recreational off-highway vehicle.
- For the purpose of these final supplementary rules, OHVs include any ATV, motorbike, specialty vehicle, or UTV not licensed for highway use (not street legal).

On BLM-administered public land within the Cove Recreation Site, you must comply with the following final supplementary rules:

1. User fees must be paid immediately upon parking or entering Cove Recreation Site. Fees must be paid at the self-service pay stations located in the campground and day-use areas. Golden Age or Golden Access Passport holders are entitled to a 50 percent fee reduction.
2. Fees for overnight camping permit two vehicles per numbered campsite. Additional vehicles will be charged an extra fee per day.
3. Camping is permitted at developed (numbered) sites only.
4. The maximum number of persons allowed on campsites is 8 for a single site, 12 for a double site, and 16 for a triple site.
5. Checkout time for overnight users is 2:00 p.m.
6. Cross-country vehicle travel within the campground is not allowed.
7. Off-highway vehicles (OHV), as defined above may not be used within the campground.
8. Vehicles and camping gear must not be left unattended in the recreation site for longer than 24 hours.
9. Quiet hours are established from 10:00 p.m. to 6:00 a.m. No loud talking, loud music, barking dogs, operation of generators, or other disturbing activities are permitted in the campground during these hours.
10. Campfires are permitted in agency-provided fire rings and grills only.
11. Cutting or collecting firewood of any kind is prohibited, including dead and down wood or other vegetative material.
12. All trash, garbage, waste, or pet fecal material must be immediately removed and disposed of in a sanitary manner. All persons must keep and leave their sites free of trash and litter at all times.
13. Dumping of graywater or blackwater is prohibited anywhere other than in an approved area.
14. Maximum length of stay in the campground is 14 consecutive days.
15. Paintball equipment must not be used or discharged in the campground or day-use areas.

Exemptions: Any Federal, State, local, and/or military employee acting within the scope of their duties; members of any organized rescue or fire-fighting force performing an official duty; and persons, agencies, municipalities or companies holding an existing special use permit and operating within the scope of their permit.

ENFORCEMENT: Any person who violates any of these supplementary rules may be tried before a United States Magistrate and fined in accordance with 18 U.S.C. 3571, imprisoned no more than 12 months under 43 U.S.C. 1733(a) and 43 CFR 8560.0–7, or both. In accordance with 43 CFR 8365.1–7, State or local officials may also impose penalties for violations of Idaho law.

Michael C. Courtney,

State Director, Idaho—Acting, Bureau of Land Management.

[FR Doc. 2016–15833 Filed 7–1–16; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM006200 L99110000.EK0000 XXX L4053RV]

Notice of Crude Helium Auction and Sale for Fiscal Year 2017 Delivery

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Secretary of the Interior (Secretary), through the Bureau of Land Management (BLM) New Mexico State Office, is issuing this Notice to conduct an auction and sale from the Federal Helium Program, administered by the BLM New Mexico Amarillo Field Office. The Helium Stewardship Act of 2013 (HSA) (Pub. L. 113–40) requires the BLM to conduct an annual auction and sale of crude helium. Accordingly, the BLM will use the auction and sale process established in 79 FR 42808, dated July 23, 2014, and further refined in 80 FR 51304, dated August 24, 2015.

DATES: Effective on July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Robert Jolley, Amarillo Field Manager, at 806–356–1002. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339. The FIRS is available 24 hours a day, 7 days a week, to leave a message. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

A. Purpose and Background

In October 2013, Congress passed the HSA. The HSA requires the Department of the Interior, through the BLM Director, to offer for auction and sale annually a portion of the helium reserves owned by the United States and stored underground at the Cliffside Gas Field, near Amarillo, Texas.

On July 23, 2014, the BLM published a "Final Notice for Implementation of Helium Stewardship Act Sales and Auctions" in the **Federal Register** (79 FR 42808) (2014 Final Notice). The 2014 Final Notice contained information about the HSA, definitions of terms used in the Notice, the reasons for the action, and a process for conducting the auctions and sales in FY 2014.

On August 24, 2015, the BLM published a "Notice of Final Action: Crude Helium Sale and Auction for Fiscal Year 2016 Delivery" in the **Federal Register** (80 FR 51304) (2015 Final Notice). The 2015 Final Notice refined the process the BLM used in 2014 for conducting the auction and sale of crude helium. The BLM will use the process set forth in the 2015 Final Notice for the auction and sale of crude helium to occur in FY 2016 for FY 2017 delivery.

Both the 2014 and 2015 Final Notices are available at the BLM helium operations Web site at: *http://www.blm.gov/nm/helium.*

B. Volumes Offered in the FY 2017 Helium Auction and Sale

Table 1 identifies the volumes to be offered for auction and sale in FY 2016 for FY 2017 delivery.

TABLE 1—PROJECTED VOLUMES FOR AUCTION AND SALES FOR FY 2017 DELIVERY

Fiscal year (FY)	Forecasted production capability (NITEC study) MMcf *	In-kind sales (sales to Federal users) MMcf	Total remaining production available for sale/auction or delivery MMcf	Volume available for auction MMcf	Volume available for non-allocated sale MMcf	Volume available for sale MMcf
FY 2017 **	1,160	160	1,000	*** 400	60	540

* MMcf means one million cubic feet of gas measured at standard conditions of 14.65 per square inch atmosphere (psia) and 60 degrees Fahrenheit.

** Delivery for FY 2017 sales and auctions will be subject to the new storage contract that began October 1, 2015.

*** 40% of total production capacity after deducting In-Kind (rounded).

C. FY 2017 Helium Auction

1.01 What is the minimum FY 2017 auction price and the FY 2017 sales price? The minimum FY 2017 auction price is $100 per Mcf (one thousand cubic feet of gas measured at standard conditions of 14.65 psia and 60 degrees Fahrenheit). The BLM will announce the FY 2017 sale price after the auction has concluded, and the BLM completes its analysis of the auction information. The BLM will use this information to publish the crude helium price for FY 2017. The BLM publishes this crude helium price, effective October 1, 2016, in order to provide a consistent index to the world-wide helium market.

1.02 What will happen to the helium offered but not sold in the helium auction? Any volume of helium offered, but not sold in the FY 2017 auction, will be added to the helium available for sale and will be offered in the FY 2017 sale.

1.03 When will the auction and sale take place? The BLM will offer helium for FY 2017 according to the following schedule:

July 20, 2016 FY 2017 helium auction held in Amarillo, Texas
July 21, 2016 FY 2017 helium auction results published on the BLM Web site
July 25, 2016 Invitation for offers (IFO) posted for helium sale
August 19, 2016 Bids due from IFO
August 25, 2016 Award announcements published on the BLM Web site
August 26, 2016 Invoices sent on or before; payments due 30 days from invoice

1.04 What is the auction format? The auction will be a live auction, held in the main conference room of the Amarillo Field Office at 1:00 p.m. central time, on July 20, 2016. The address is 801 South Fillmore, Suite 500, Amarillo, TX 79101. Anyone meeting the HSA definition of a qualified bidder may participate in the auction. The logistics for the auction and the pre-bid qualification form is included in a document entitled, "Auction Guide" at *www.blm.gov/nm/helium2017.* Questions related to the auction can be submitted by phone to the BLM at 806–356–1001.

1.05 Who is qualified to purchase helium at the auction? Only qualified bidders, as defined in 50 U.S.C. 167(9), may participate in and purchase helium at the auction. The BLM will make the final determination of who is a qualified bidder using the HSA's definition of a qualified bidder, regardless of whether or not that person was previously determined to be a qualified bidder.

1.06 How many helium lots does the BLM anticipate offering at the FY 2017 auction? The BLM anticipates auctioning 400 MMcf in a total of 24 lots for FY 2017. The lots would be divided as follows:

10 lots of 25 MMcf each;
8 lots of 15 MMcf each; and
6 lots of 5 MMcf each.

1.07 What must I do to bid at auction? The BLM has described the live auction procedures, including detailed bidding instructions and pre-bid registration requirements, in a document entitled, "FY 2017 Auction Notice and Guide" at *www.blm.gov/nm/helium2017.*

1.08 When will helium that is purchased at sale or won at auction be available in the purchaser's storage account? The BLM will transfer the volumes purchased in the FY 2017 auction and sale to the buyer's storage accounts beginning on the first day of the month following receipt of payment.

D. FY 2017 Helium Sale

2.01 Who will be allowed to purchase helium in the FY 2017 sale? The crude helium sale will be separated into two distinct portions, a non-allocated portion and an allocated portion. The non-allocated portion will be ten percent of the total amount offered for sale for FY 2017, and will be available to those storage contract holders, as of June 30, 2016, who do not have ability to accept delivery of crude helium from the Federal Helium Pipeline (as defined in 50 U.S.C. 167(2)). The allocated portion will be ninety percent of the total amount offered for sale for FY 2017, and will be available to any person (including individuals, corporations, partnerships, or other entities) with the ability to accept delivery of crude helium from the Federal Helium Pipeline (as defined in 50 U.S.C. 167(2)).

2.02 How will helium sold in the FY 2017 sale be allocated among those participating in the non-allocated sale? The non-allocated sale will be made available to all qualified offerors not eligible to participate in the allocated sales. The minimum volume that can be requested is 1 MMcf. The total volume available for the non-allocated portion of the sale is 40 MMcf. Any volumes not sold at auction will be distributed between the non-allocated (10 percent) and the allocated sale (90 percent). Any volumes not purchased at the non-allocated sale will be sold in the allocated portion.

2.03 How will the helium sold in the FY 2017 sale be allocated among the persons to accept delivery of crude helium from the Federal Helium Pipeline? Any person wishing to participate in the allocated portion of the FY 2017 sale needs to report its excess refining capacity and operational capacity by June 30, 2016, using the Excess Refining Capacity form, which can be downloaded at: *http://www.blm.gov/nm/heliumreporting,* or in a link entitled "Required Forms for Helium Reporting" at *www.blm.gov/nm/helium2017.* Each person participating in the sale will then be allocated a proportional share based upon that person's operational capacity.

2.04 How does a person apply for access to the Federal Helium Pipeline for the purpose of taking crude helium? The steps for taking crude helium are provided in the BLM's Helium Operations Web site in a document entitled, "How to Set Up a Storage Account and Pipeline Access" at *http://www.blm.gov/nm/helium2017.* Reporting forms show the due dates for each report, and can be found in a document entitled, "Required Forms for Helium Reporting" at *www.blm.gov/nm/helium2017.* The length of time required to apply for and obtain access to the Federal Helium Pipeline vary based on the person's plans for plant construction, pipeline metering installation, and other variables. The BLM is available to provide technical assistance, including contact information for applying for access and meeting any applicable National Environmental Policy Act requirements.

E. Delivery of Helium in FY 2017

3.01 When will I receive the helium that I purchase in a sale or win based on a successful auction bid? Helium purchased at the FY 2017 sale or won at the FY 2017 auction will be delivered starting October 1, 2016, in accordance with the crude helium storage contract. The intent is to ensure delivery of all helium purchased at sale or auction up to the BLM's production capability for the year.

3.02 How will the BLM prioritize delivery? The HSA gives priority to Federal in-kind helium (*i.e.,* helium sold to Federal users) (50 U.S.C. 167d(b)(1)(D)) and (b)(3)). After meeting that priority, the BLM will make delivery on a reasonable basis, as described in the crude helium storage contract, to ensure storage contract holders who have purchased or won helium at auction have the opportunity during the year to have that helium produced or refined in monthly increments.

F. Background Documents

Supplementary documents referenced in this Notice are available at the BLM helium operations Web site at: *http://www.blm.gov/nm/helium2017,* and include the following:

a. The HSA (50 U.S.C. 167);
b. FY 2017 Helium Auction Notice and Guide;
c. Table of Projected Volumes for Sales and Auctions for Delivery for FY 2017–FY 2021 (informational);
d. Hypothetical example of how the FY 2017 Allocated Sale would be conducted (informational);
e. Hypothetical example of how the FY 2017 Non-Allocated Sale would be conducted (informational);
f. Schedule for Helium Auction and Sale;
g. How to Set Up a Storage Account and Pipeline Access;
h. 2016 Reference Helium Storage Contract (informational); and
i. Required Forms for Helium Reporting.

Authority: The HSA of 2013 (Public Law 113–40) codified to various sections in 50 U.S.C. 167–167q.

Aden Seidlitz,
Associate State Director.

[FR Doc. 2016–15754 Filed 7–1–16; 8:45 am]
BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

Notice of Availability of a Final Supplemental Environmental Impact Statement for the Jamul Indian Village Proposed Gaming Management Agreement, San Diego County, California

AGENCY: National Indian Gaming Commission (NIGC), Interior.

ACTION: Notice of Availability (NOA).

SUMMARY: In accordance with Section 102(2)(C) of the National Environmental Policy Act (NEPA) 42 U.S.C. 4321 *et seq.,* the NIGC, in cooperation with the Jamul Indian Village has prepared a Final Supplemental Environmental Impact Statement (Final SEIS) for the proposed Gaming Management Agreement (GMA) between the Jamul Indian Village (JIV) and San Diego Gaming Ventures (SDGV). If approved, the GMA would allow SDGV to assume responsibility for operation and management of the JIV Gaming Facility located in San Diego County, California. The Final SEIS addresses the effects of GMA approval and the No Action Alternative, which assumes no GMA, is

approved. The SEIS also updates the environmental baseline given the time that has passed and the changes that have been made to the scope of the Proposed Action, which was originally addressed in the 2003 Final EIS.

FOR FURTHER INFORMATION CONTACT: For further information or to request a copy of the Final SEIS, please contact: Andrew Mendoza, Staff Attorney, National Indian Gaming Commission, Office of the General Counsel, 1849 C Street NW., Mail Stop #1621, Washington, DC 20240, Phone: 202–632–7003: Facsimile: 202–632–7066: email: *Andrew_Mendoza@nigc.gov*

Availability of the Final SEIS: The Final SEIS is available for public review at the following locations:

—The Rancho San Diego Public Library, 11555 Via Rancho San Diego, El Cajon, CA 92019, telephone (619) 660–5370; and

—The Jamul Indian Village Tribal Office, 14191 #16 Highway 94, Jamul, CA 91935, telephone (619) 669–4785.

Copies of the Final SEIS will also be available for download from the Tribe's Web site *www.jamulindianvillage.com.*

SUPPLEMENTARY INFORMATION: The JIV Reservation is located in the unincorporated portion of southwestern San Diego County approximately one mile south of the community of Jamul on approximately six-acres of land held in federal trust. State Route 94 (SR–94) provides regional access to the JIV from downtown San Diego, which is located approximately 20 miles to the west where it intersects with Highway 5. Local access to the JIV is provided directly from SR–94 via Daisy Drive. From the JIV, SR–94 travels briefly north and then west to Downtown San Diego, passing through the unincorporated communities of Jamul, Casa de Oro, Spring Valley and Lemon Grove.

In 2000, JIV proposed a fee-to-trust land acquisition, construction and operation of a gaming complex and approval of a gaming development and management agreement for operation of the JIV Gaming Facility. The proposal was evaluated in a Final EIS prepared in 2003. Since that time, several major items have been removed from JIV's overall development program and the Gaming Facility has been redesigned to fit entirely within the existing JIV Reservation. All environmental effects of the Gaming Facility redesign have been evaluated through preparation of a Final Tribal Environmental Evaluation, which was prepared in accordance with the 1999 Tribal/State Compact. No action is before the BIA due to no fee-to-trust component of the JIV proposal. An action from the NIGC is required; specifically, approval or disapproval of the GMA. That approval or disapproval is the Proposed Action evaluated in the Final SEIS.

In addition to the Proposed Action, the Final SEIS addresses the No Action Alternative, which assumes no approval of the GMA between JIV and SDGV. Under the No Project scenario, JIV would assume operation and management responsibilities of the Jamul Gaming Facility. The NIGC may, in its Record of Decision, select the No Project Alternative rather than the Proposed Action.

This Final SEIS updates environmental conditions in the affected area given the amount of time that has passed since the 2003 Final EIS. Environmental issues addressed within the Final SEIS include land resources, water resources, air quality, biological resources, cultural/paleontological resources, socioeconomic conditions, transportation, land use, public services, hazardous materials, noise, and visual resources. The Final SEIS examines the direct, indirect, and cumulative effects of each alternative on these resources. The NIGC published a Notice of Intent (NOI) in the **Federal Register** on April 10, 2013, describing the Proposed Action, announcing the NIGC's intent to prepare a Draft SEIS for the Proposed Action, and inviting comments.

The Draft EIS Notice of Availability (NOA) was published in the **Federal Register** by the U.S. Environmental Protection Agency (EPA) on April 8, 2016 and the Draft SEIS was made available to federal, Tribal, state, and local agencies and other interested parties for review and comment. The comment period was open for 45 days after the date of publication in the **Federal Register** and closed on May 23, 2016. A total of nine comment letters were received. All comments received by the NIGC were considered and addressed in the Final SEIS, however, no substantive changes were made.

Upon conclusion of the 30-day public availability period following the date the EPA publishes the NOA for the Final SEIS in the **Federal Register**, the Chairman of the NIGC will prepare and sign the record of decision (ROD) to announce his final decision on the GMA between the JIV and SDGV. Availability of the ROD will be announced to the media and the project mailing list, and the ROD itself will be made available online.

Submittal of Written Comments: You may mail or email, written comments to NIGC, Attn: Andrew Mendoza, Staff Attorney, c/o Department of the Interior, 1849 C Street NW., Mail Stop #1621, Washington, DC 20240, email: *Andrew_Mendoza@nigc.gov.* Please include your name, return address, and the caption: "Final SEIS Comments, Jamul Indian Village," on the first page of your written comments. In order to be fully considered, written comments on the Final SEIS must be postmarked by August 4, 2016.

Commenting individuals may request confidentiality. If you wish us to withhold your name and/or address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comments. Such requests will be honored to the extent allowed by law. Anonymous comments will not, however, be considered. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available to public in their entirety.

Authority: This notice is published in accordance with 25 U.S.C. 2711, section 1503.1 of the Council on Environmental Quality Regulations (40 CFR parts 1500 through 1508), and the Department of the Interior regulations (43 CFR part 46), implementing the procedural requirements of NEPA, as amended (42 U.S.C. 4321 *et seq.*).

Dated: June 29, 2016.

Shannon O'Loughlin,

Chief of Staff.

[FR Doc. 2016–15847 Filed 7–1–16; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21346; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Field Museum of Natural History, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Field Museum of Natural History, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of sacred objects. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to The Field Museum of Natural History. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to The Field Museum of Natural History at the address in this notice by August 4, 2016.

ADDRESSES: Helen Robbins, Repatriation Director, The Field Museum of Natural History, 1400 South Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7317, email *hrobbins@fieldmuseum.org.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of The Field Museum of Natural History, Chicago, IL, which meet the definition of sacred objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item(s)

In 1916, a buckskin dance skirt from the Smith River in Del Norte County, CA, represented by catalog number 62628, was accessioned by The Field Museum of Natural History. Museum records indicate that this item is Tolowa in origin. The source for this cultural item was recorded as "Old Ned's Wife," likely collected by Grace Nicholson. This item was gifted to the Museum by Edward Ayer, who is presumed to have purchased the skirt from Ms. Nicholson in her Pasadena store. It is possible that this item was collected prior to the museum accession date.

In 1918, a Gala buckskin dress, represented by catalog number 62997, and a buckskin headband, represented by catalog number 62999, both from California, were accessioned by The Field Museum. Museum records indicate that these items are Tolowa in origin, and were purchased by Edward Ayer from Grace Nicholson's collection in Pasadena. It is possible that these items were collected prior to the museum accession date.

The buckskin dance skirt and the Gala buckskin dress were historically and are presently used by young women in a number of Tolowa ceremonies, including the World Renewal Ceremony (Nee-dash) and Puberty Ceremony. The buckskin headdress was and is used by men and boys during the same ceremonies. The role and significance of these ceremonial items to the people of northern California has been confirmed through consultation with the Tolowa Dee-ni' Nation, numerous ethnographic texts, and the contemporary records and publications of various museums, both in terms of their religious importance to the individual wearer and to the Tolowa Dee-ni' Nation (Tolowa people).

The Tolowa Dee-ni' are culturally affiliated with the area from which the sacred objects were removed. This is supported by consultation with the Tolowa Dee-ni' Nation and other northern California nations, Department of the Interior sources, and academic publications that closely detail genocide, relocations, political organization, and cultural practice over the course of northern California history from the 1800s to the present.

Determinations Made by The Field Museum of Natural History

Officials of The Field Museum of Natural History have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), the three cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the sacred objects and the Tolowa Dee-ni' Nation (previously listed as the Smith River Rancheria, California).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Helen Robbins, Repatriation Director, The Field Museum of Natural History, 1400 S. Lake Shore Dr., Chicago, IL 60605, telephone (312) 665–7317, email *hrobbins@fieldmuseum.org,* by August 4, 2016. After that date, if no additional claimants have come forward, transfer of control of the sacred objects to the Tolowa Dee-ni' Nation (previously listed as the Smith River Rancheria, California) may proceed.

The Field Museum of Natural History is responsible for notifying the Big Lagoon Rancheria, California; the Blue Lake Rancheria, California; the Elk Valley Rancheria, California; the Tolowa Dee-ni' Nation (previously listed as the Smith River Rancheria, California); and the Cher-Ae Heights Indian Community of the Trinidad Rancheria, California, that this notice has been published.

Dated: June 20, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–15843 Filed 7–1–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21332; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: University of Pennsylvania Museum of Archaeology and Anthropology, Philadelphia, PA; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The University of Pennsylvania Museum of Archaeology and Anthropology has corrected a Notice of Inventory Completion published in the **Federal Register** on June 8, 2016. This notice adds accession numbers to the description of the human remains and adds two Indian tribes to be notified of the publication.

ADDRESSES: Dr. Julian Siggers, University of Pennsylvania Museum of Archaeology and Anthropology, 3260 South Street, Philadelphia, PA 19104, telephone (215) 898–4050.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of a Notice of Inventory Completion for human remains under the control of the University of Pennsylvania Museum of Archaeology and Anthropology, Philadelphia, PA. The human remains were removed from an unknown site in Wayne County, MI, and Cuyahoga County, OH.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the description of the human remains and the Indian tribes to be notified of publication in a Notice of Inventory Completion published in the **Federal Register** (81 FR 36952, June 8, 2016). Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (81 FR 36953, June 8, 2016), column 2, paragraph 2, sentence 1 is corrected by substituting the following sentence:

> In1844, human remains representing, at minimum, two individuals (UPM# 97–606–1217; UPM#97–606–1218) were removed by Lt. Montgomery C. Meigs from an unknown Mound site in Wayne County, MI.

In the **Federal Register** (81 FR 36953, June 8, 2016), column 2, paragraph 3, sentence 1 is corrected by substituting the following sentence:

> At an unknown date prior to 1839, human remains representing, at minimum, one individual (UPM#97–606–607) were removed by Dr. George Mendenhall from an unknown site in Cuyahoga County, OH, and were sent to Samuel G. Morton for inclusion in his collection of human crania from around the world prior to 1846.

In the **Federal Register** (81 FR 36953, June 8, 2016), column 2, paragraph 4, sentence 1 is corrected by substituting the following sentence:

> At an unknown date prior to 1839, human remains representing, at minimum, one individual (UPM# 97–606–15) were removed by Dr. Sturum from an unknown location near Detroit, Wayne County, MI.

In the **Federal Register** (81 FR 36954, June 8, 2016), column 1, paragraph 1, sentence 1 is corrected by substituting the following sentence:

> The University of Pennsylvania Museum of Archaeology and Anthropology is responsible for notifying the Bay Mills Indian Community, Michigan; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Nottawaseppi Huron Band of the Pottawatomi, Michigan (previously listed as the Huron Potawatomi, Inc.); Pokagon Band of Potawatomi Indians, Michigan and Indiana; Saginaw Chippewa Indian Tribe of Michigan; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; and the Wyandotte Nation, that this notice has been published.

The University of Pennsylvania Museum of Archaeology and Anthropology is responsible for notifying the Bay Mills Indian Community, Michigan; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Nottawaseppi Huron Band of the Pottawatomi, Michigan (previously listed as the Huron Potawatomi, Inc.); Pokagon Band of Potawatomi Indians, Michigan and Indiana; Saginaw Chippewa Indian Tribe of Michigan; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; and the Wyandotte Nation that this notice has been published.

Dated: June 17, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–15840 Filed 7–1–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21327; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Stanford University Heritage Services, Palo Alto, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Stanford University Heritage Services has completed an inventory of the human remains of a Native American individual in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has identified a lineal descendant of this Native American indvidual. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to Stanford University Heritage Services. If no additional requestors come forward, transfer of control of the human remains to the lineal descendant stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Stanford University Heritage Services at the address in this notice by August 4, 2016.

ADDRESSES: Dr. Laura Jones, Stanford University Heritage Services, 3160 Porter Drive, Suite 200, Palo Alto, CA 94304, telephone (650) 723–9664, email *ljones@stanford.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Stanford University Planning Office, Palo Alto, CA. The human remains were removed from Longville, Humbug Valley, in Plumas County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Stanford University Heritage Services professional staff in consultation with representatives of the Greenville Rancheria (previously listed as the Greenville Rancheria of Maidu Indians of California); the Susanville Indian Rancheria, California; the Maidu Summit Consortium (a non-federally recognized Indian group); and with Ms. Beverly Ogle, an individual.

History and Description of the Remains

In October 1895, human remains representing, at minimum, one individual were removed from a historic cemetery in Longville, Plumas County, CA. Excavations were carried out by Stanford University alumna, Mabel Louise Miller in 1895. She is known to have excavated a Native American cemetery abandoned around 1853 and located at a rancheria near Longville, in Plumas County. Miller gave the human remains to the Leland Stanford Junior Museum in October 1916 and subsequently, the museum transferred them to the Stanford University Department of Anthropology. Currently, the human remains are housed in the Stanford University Archaeology Collections. The cemetery was located with the assistance of Ms. Beverly Ogle and was used exclusively by Ms. Ogle's family. It lay adjacent to the home of Ms. Ogle's great-grandfather, Fred Thomas, in the former town site of Longville. Ms. Ogle's family used this small cemetery in the middle to late 1800s.

Determinations Made by the Stanford University Heritage Services Office

Officials of the Stanford University Heritage Services office have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 43 CFR 10.10(b)(1) and 43 CFR 10.14(b), Beverly Ogle is a lineal descendant of the human remains removed from the specific burial site.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Laura Jones, Stanford University Heritage Services, 3160 Porter Drive, Suite 200, Palo Alto, CA 94304, telephone (650) 723–9664, email *ljones@stanford.edu,* by August 4, 2016. After that date, if no additional requestors have come forward, transfer of control of the human remains to Beverly Ogle may proceed.

The Stanford University Heritage Services office is responsible for notifying the representatives of Greenville Rancheria (previously listed as the Greenville Rancheria of Maidu Indians of California); the Susanville Indian Rancheria, California; the Maidu Summit Consortium (a non-federally recognized Indian group); and Ms. Beverly Ogle that this notice has published.

Dated: June 16, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–15839 Filed 7–1–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21326; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Stanford University Heritage Services, Palo Alto, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: Stanford University Heritage Services, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to Stanford University Heritage Services. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendant stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Stanford University Heritage Services at the address in this notice by August 4, 2016.

ADDRESSES: Dr. Laura Jones, Stanford University Heritage Services, 3160 Porter Drive, Suite 200, Palo Alto, CA 94304, telephone (650) 723–9664, email *ljones@stanford.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Stanford University Planning Office, Palo Alto, CA, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In October 1895, 21 cultural items were removed from a historic cemetery in Longville, Plumas County, CA. Excavations were carried out by Stanford University alumna, Mabel Louise Miller in 1895. She is known to have excavated a Native American cemetery abandoned around 1853 and located at a rancheria near Longville, in Plumas County. Miller gave the objects to the Leland Stanford Junior Museum in October 1916, and subsequently, the Museum transferred them to the Stanford University Department of Anthropology. Currently, the objects are housed in the Stanford University Archaeology Collections. The location of the human remains of the individual with whom the objects were placed is not known. The 21 unassociated funerary objects include 1 ferrous knife, 11 shell ornaments, 1 projectile point, 6 flakes, 1 hammerstone, and 1 string of shell beads.

The funerary objects were determined to be affiliated with the Mountain Maidu based on documentation provided by Mabel Miller and consultation with representatives of the Greenville Rancheria (previously listed as the Greenville Rancheria of Maidu Indians of California), the Susanville Indian Rancheria, California, and with individual members of Mountain Maidu groups (Beverly Ogle, Trina Cunningham, and Melany Johnson). Beverly Ogle, whose family had exclusive use of the Longville cemetery, has requested the repatriation of these unassociated funerary objects as a lineal descendant of the individual with whom they were placed and has provided information sufficient to show her lineal descent from the Native American individuals buried in her family's small cemetery during the middle to late 1800s.

Determinations Made by Stanford University Heritage Services

Officials of Stanford University Heritage Services have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 21 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 43 CFR 10.10(a)(1) and 43 CFR 10.14(b), Beverly Ogle is a lineal descendant of the individual with whom the 21 unassociated funerary objects were placed, and whose human remains are not under the control of Stanford University Heritage Services.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Dr. Laura Jones, Stanford University Heritage Services, 3160 Porter Drive, Suite 200, Palo Alto, CA 94304, telephone (650) 723–9664, email *ljones@stanford.edu,* by August 4, 2016. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to Beverly Ogle may proceed.

Stanford University Heritage Services is responsible for notifying Beverly Ogle, Trina Cunningham, and Melany Johnson that this notice has been published.

Dated: June 16, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–15838 Filed 7–1–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21347; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Office of the State Archaeologist, University of Iowa, Iowa City, IA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Office of the State Archaeologist Bioarchaeology Program, previously listed as the Office of the State Archaeologist Burials Program, has completed an inventory of human remains, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Office of the State Archaeologist Bioarchaeology Program. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Office of the State Archaeologist Bioarchaeology Program at the address in this notice by August 4, 2016.

ADDRESSES: Dr. Lara Noldner, Office of the State Archaeologist Bioarchaeology Program, University of Iowa, 700 South Clinton Street, Iowa City, IA 52242, telephone (319) 384–0740, email *lara-noldner@uiowa.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Office of the State Archaeologist Bioarchaeology Program, University of Iowa, Iowa City, IA. The human remains were removed from Northern California.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Office of the State Archaeologist Bioarchaeology Program professional staff in consultation with the Native American Heritage Commission and representatives of the Big Sandy Rancheria of Western Mono Indians of California (previously listed as the Big Sandy Rancheria of Mono Indians of California); the Chicken Ranch Rancheria of Me-Wuk Indians of California; the Cold Springs Rancheria of Mono Indians of California; the Ione Band of Miwok Indians of California; the Jackson Band of Miwuk Indians (previously listed as the Jackson Rancheria of Me-Wuk Indians of California); the Northfork Rancheria of Mono Indians of California; the Santa Rosa Indian Community of the Santa Rosa Rancheria, California; the Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; the Table Mountain Rancheria of California; the Tule River Indian Tribe of the Tule River Reservation, California; and the Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California, hereafter referred to as "The Tribes".

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown location, possibly in Northern California. The human remains were held by a private citizen, whose son donated the human remains to the Office of the State Archaeologist Bioarchaeology Program in May 1997. The cranial remains represent an adult male, approximately 25 to 35 years old (Burial Project 1135). No known individuals were identified. No associated funerary objects are present.

The overall condition of the bone suggests antiquity. Cranio-facial morphology and dental wear indicate the individual is Native American. Limited provenience information indicates the human remains are from northern California, a region occupied by Yokut-speaking peoples well before European contact. Archeological, linguistic, ethnographic and oral historical evidence suggests that the Yokuts and their ancestors inhabited the region since 500 B.C.

Determinations Made by the Office of the State Archaeologist Bioarchaeology Program

Officials of the Office of the State Archaeologist Bioarchaeology Program have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Lara Noldner, Office of the State Archaeologist Bioarchaeology Program, University of Iowa, 700 S Clinton Street, Iowa City, IA 52242, telephone (319) 384–0740, email *lara-noldner@uiowa.edu,* by August 4, 2016. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Office of the State Archaeologist Bioarchaeology Program is responsible for notifying The Tribes that this notice has been published.

Dated: June 20, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–15841 Filed 7–1–16; 8:45 am]

BILLING CODE 4312–50–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–958]

Certain Automated Teller Machines and Point of Sale Devices and Components Thereof; Termination of an Investigation on the Basis of Withdrawal of the Complaint

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 19), which granted a motion to terminate the investigation in its entirety based upon withdrawal of the complaint. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2532. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 9, 2015, based on a complaint filed by Global Cash Access, Inc. of Las Vegas, Nevada, alleging a violation of section 337 by virtue of the infringement of claims 1–3, 5–7 and 9 of U.S. Patent No. 6,081,792 ("the '792 patent") and by virtue of false advertising. 80 FR 32,605. The notice of investigation named as respondents NRT Technology Corp. of Toronto, Ontario; and NRT Technologies, Inc. of Las Vegas, Nevada (collectively, "NRT"). On October 9, 2015, the Commission determined not to review an initial determination (Order No. 9) granting the complainant's motion to amend the complaint to change the complainant's name to Everi Payments Inc. ("Everi"), in view of a corporate name change. On May 16, 2016, the Commission determined to review, and on review affirm, an initial determination (Order No. 17) finding the asserted claims of the '792 patent invalid as indefinite pursuant to 35 U.S.C. 112.

On June 1, 2016, Everi filed an unopposed motion to terminate the investigation in its entirety by withdrawal of the complaint. *See* 19 CFR 210.21(a)(1). On June 2, 2016, the ALJ granted the motion as the subject initial determination ("ID") (Order No. 19). The ALJ found that Everi's motion complied with Commission rules. Order No. 19 at 1–2.

No petitions for review were filed. The Commission has determined not to review the ID. The investigation is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: June 29, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–15803 Filed 7–1–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1070B (Second Review)]

Certain Tissue Paper Products From China

Determination

On the basis of the record[1] developed in the subject five-year review, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that revocation of the antidumping duty order on certain tissue paper products from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission, pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)), instituted this review on June 1, 2015 (80 FR 31065) and determined on September 4, 2015 that it would conduct a full review (80 FR 57386, September 23, 2015). Notice of the scheduling of the Commission's review and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on January 13, 2016 (81 FR 1643). The hearing was cancelled at the request of the domestic interested parties. The notice of cancellation of the hearing was published in the **Federal Register** on April 18, 2016 (81 FR 22632).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on June 23, 2016. The views of the Commission are contained in USITC Publication 4617 (June 2016), entitled *Certain Tissue Paper Products from China: Investigation No. 731–TA–1070B (Second Review).*

By order of the Commission.

Issued: June 23, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–15822 Filed 7–1–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[Docket No. OIP–0001]

Notice of Chief Freedom of Information Act Officer Council Meeting

AGENCY: Department of Justice.

ACTION: Notice of Chief FOIA Officer Council meeting.

SUMMARY: In accordance with the Freedom of Information Act (5 U.S.C. 552(k), DOJ announces the first meeting of the newly formed Chief FOIA Officer Council. Additional details about the meeting will be announced on OIP's Web sites at: *https://www.justice.gov/oip.*

DATES: The meeting will be on July 22, 2016, at 2:00 p.m. EDT. You must register for the meeting by 5:00 p.m. EDT on July 15, 2016.

Location: Eisenhower Executive Office Building; 1650 Pennsylvania Avenue NW., Washington, DC 20502.

FOR FURTHER INFORMATION CONTACT: OIP by mail at Department of Justice; Office of Information Policy; 1425 New York Avenue NW., Suite 11050, Washington, DC 20530–001, by telephone at 202–514–3642, or by email at

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[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DOJ.OIP.FOIA@usdoj.gov with the subject line: "Chief FOIA Officer Council."

SUPPLEMENTARY INFORMATION: Additional details about the meeting will be announced on OIP's Web sites at: *https://www.justice.gov/oip.* Additional Information: The Council welcomes the attendance of the public at this meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations, please indicate your requirements on the online registration form.

Dated: June 30, 2016.

Carmen L. Mallon,

Chief of Staff, Office of Information Policy.

[FR Doc. 2016–16000 Filed 7–1–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1712]

Unmanned Aircraft Systems Evaluation

AGENCY: National Institute of Justice (NIJ), Justice.

ACTION: Notice of request for information.

SUMMARY: NIJ is soliciting information on the operational use of Unmanned Aircraft Systems (UAS) in support of law enforcement. The focus of the study is on the use of UAS for crash scene reconstruction; however, information on alternative uses of UAS in law enforcement is also requested.

The National Criminal Justice Research, Test and Evaluation Center (NIJ RT&E Center) is performing an operational evaluation of UAS for Crash Scene Reconstruction. The objective of this evaluation is to evaluate the utility of a UAS to support crash scene reconstruction in an operational law-enforcement setting. In particular, the study will determine whether a UAS could be used to improve crash scene reconstruction in terms of quality, safety, timeliness, or other metrics. Based upon previous investigations, the Center has identified a number of agencies that have operational UAS capabilities configured to support law enforcement. The Center is now seeking to partner with those or other interested agencies in order to complete the operational evaluation.

Information Sought: The Center is seeking law enforcement agencies with which to partner in an operational evaluation of UAS technology for Crash Scene Reconstruction. This evaluation will, at the discretion of the partnering agency, occur during normal operations or during scheduled exercises. Agencies or vendors who respond to this request for information are invited to provide general comments with regard to the evaluation for NIJ RT&E Center to consider, including which uses of the system and which performance metrics are appropriate for the evaluation. It should be noted that the purpose of the evaluation is to assess the utility of UAS technology; this includes assessment of both current and possible future practices. The Center is not evaluating the participating law enforcement agencies, just the application of using UAS for Crash Scene Reconstruction. Information will be obtained through responses to the information requested below as a baseline for initial information gathering from responding law enforcement agencies. Follow up discussions will be conducted in some cases. The request for information is intended to reach a consistent understanding of the needs for UAS for Crash Scene Reconstruction and the ways each agency uses the technology.

Information sought includes the following:

1. Law Enforcement Agency Information
   a. Agency Name
   b. Agency Location
   c. Agency Point of Contact
   d. Number of crash scene reconstructions in the past year
   e. Primary tools used for crash scene reconstruction
   f. Number of crash scene reconstructions in the past year using UAS only
   g. Number of certified reconstructionists on staff
   h. Total number of operational flights since your agency's implementation of the UAS
   i. Number of operational flights in the past year
   j. Future plans for operational use of UAS
   k. Federal Aviation Administration Certificates of Waiver or Authorization documentation, if applicable
2. UAS Technology Information
   a. UAS Vendor Name, System Name, and Model Number (may be plural)
   b. Sensors available
   c. Current sensor use
   d. List of additional components and accessories
   e. Previous system deployment scenarios or locations
   f. Types of data currently stored in reconstruction records database
   g. Personnel/operators required and training
   h. Manufacturer suggested retail price, without optional features, accessories or service plans
   i. Any additional information not covered above
3. Current and planned capabilities
   a. Types of Crash Scene Reconstruction data collected by UAS
   b. Capabilities to support a forensically sound process for preserving the integrity of collected data for use as evidence
   c. Types of analytic techniques used (*e.g.,* photogrammetry, 3D modeling) and methods used to preserve evidentiary value of analytical results
   d. Installation, Start-up, Launch, and tear-down times
   e. Type of data output and processes used to ensure its forensic value
   f. Types of real-time monitoring features
   g. Other features or capabilities not covered above

Protection of Sensitive Information: Organizations responding to this request for information should be aware of the following guidelines for handling of information:

1. The NIJ RT&E Center does not require or desire access to privileged information. For example, while the Center has interest in data pertaining to reconstruction, such as road closure time, tools utilized, and manpower, the Center has no interest in sensitive information, such as names or other Personally Identifiable Information. The Center will work with participating organizations to prevent disclosure of sensitive private information to the representatives of the NIJ RT&E Center.

2. Results of the operational evaluation will be published to ensure maximum usefulness to the law enforcement community. Participating law enforcement organizations will be provided an opportunity to review documents prior to any public release to ensure that the content of these documents does not in any way compromise their operations.

DATES: Responses to this request will be accepted through 11:59 p.m. Eastern Time on August 31, 2016.

ADDRESSES: Responses to this request may be submitted electronically in the body of or as an attachment to an email sent to *administrator@nijrtecenter.org* with the recommended subject line "UAS Federal Register Response." Questions and responses may also be sent by mail (please allow additional time for processing) to the address: National Criminal Justice Research, Test and Evaluation Center, ATTN: UAS Federal Register Response, Johns Hopkins University Applied Physics Laboratory, 11100 Johns Hopkins Road, Mail Stop 17N444, Laurel, MD 20723–6099.

FOR FURTHER INFORMATION CONTACT: For more information on this request for information contact Emre Gunduzhan (NIJ RT&E Center) at (240) 228–7269 or *administrator@nijrtecenter.org.* For more information on the NIJ RT&E Center, visit *http://nij.gov/funding/awards/pages/award-detail.aspx?award=2013-MU-CX-K111* and view the description or contact Martin Novak (NIJ Research Division) at (202) 598–7795. Please note that these are not toll-free telephone numbers.

Nancy Rodriguez,

Director, National Institute of Justice.

[FR Doc. 2016–15804 Filed 7–1–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Availability of Funds and Funding Opportunity Announcement for Disability Employment Initiative Cooperative Agreements

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of Funding Opportunity Announcement (FOA).

Funding Opportunity Number: FOA–ETA–16–07.

SUMMARY: The Employment and Training Administration (ETA), U.S. Department of Labor (DOL, or the Department, or we), announces the availability of approximately $15.6 million in grant funds authorized by Section 169, subsection (b), of the Workforce Innovation and Opportunity Act (WIOA).

The purpose of this program is to provide funding to expand the capacity of American Job Centers (AJCs), also known as One-Stop Centers, to improve the employment outcomes of three population focus areas: (1) Adults (ages 18 and older) with visible and non-visible disabilities, including those who have acquired disabilities in adulthood; (2) youth (ages 14–24) with visible and non-visible disabilities, including those who have chronic health conditions; and (3) individuals (ages 14 and older) with significant disabilities. The DEI plans to accomplish this by increasing their participation in career pathways systems and successful existing programs in the public workforce system in partnership with vocational rehabilitation, community colleges and other education, human service, and business partners. Capitalizing on the flexibility that the career pathways model provides to use innovative service delivery strategies, grantees will use their award to support job-driven approaches in their pre-existing career pathway systems and programs. This will further equip individuals with disabilities with the skills, competencies, and credentials necessary to help them obtain in-demand jobs, increase earnings, and advance their careers.

The Department intends to award at least one cooperative agreement in each of three population focus areas: (1) Adults (ages 18 and older) with visible and non-visible disabilities, including those who have acquired disabilities in adulthood; (2) youth (ages 14–24) with visible and non-visible disabilities, including those who have chronic health conditions; and (3) individuals (ages 14 and older) with significant disabilities.

We expect to fund approximately 8 cooperative agreements (as defined in 2 CFR 200.24) to state workforce agencies, ranging from $1.5 million to $2.5 million each. Applicants may also include entities receiving funds under WIOA Section 166 grants. An eligible applicant is a tribe, tribal consortium, or tribal non-profit organization that receives funds under WIOA Section 166 Indian and Native American Program. States that received DEI Round VI funds are not eligible for funding under this FOA.

The complete FOA and any subsequent FOA amendments in connection with this funding opportunity are described in further detail on ETA's Web site at *https://www.doleta.gov/grants/find_grants.cfm* or on *http://www.grants.gov.* The Web sites provide application information, eligibility requirements, review and selection procedures, and other program requirements governing this funding opportunity.

DATES: The closing date for receipt of applications under this announcement is August 1, 2016. Applications must be received no later than 4:00:00 p.m. Eastern Time.

FOR FURTHER INFORMATION CONTACT: Erika Beasley, 200 Constitution Avenue NW., Room N–4716, Washington, DC 20210; Telephone: 202–693–3906.

Jimmie Curtis is the Grant Officer for the Funding Opportunity Announcement.

Signed June 29, 2016, in Washington, DC.

Donna Kelly,

Grant Officer, Employment and Training Administration.

[FR Doc. 2016–15830 Filed 7–1–16; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Prepare an Environmental Impact Statement and Initiate Consultation for Proposed Changes to Sacramento Peak Observatory Operations, Sunspot, New Mexico; Notice of Public Scoping Meetings and Comment Period

AGENCY: National Science Foundation.

ACTION: Notice of intent to prepare an environmental impact statement and public scoping meetings and comment period.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended, the National Science Foundation (NSF) intends to prepare an environmental impact statement (EIS) to evaluate potential environmental effects of proposed changes to operations at Sacramento Peak Observatory, in Sunspot, New Mexico. (See **SUPPLEMENTARY INFORMATION** below for more detail.) By this notice, NSF is announcing the beginning of the scoping process to solicit public comments and identify issues to be analyzed in the EIS. At this juncture, NSF would welcome public comments on the preliminary proposed alternatives and resource areas identified for analysis. NSF also intends to initiate consultation under section 106 of the National Historic Preservation Act to evaluate potential effects to the Sacramento Peak Observatory.

DATES: This notice initiates the public scoping process for the EIS and the initiation of public involvement under section 106 per 36 CFR 800.2(d). Comments on issues may be submitted verbally during the scoping meeting scheduled for July 21, 2016 (see details in **SUPPLEMENTARY INFORMATION**), or in writing until August 5, 2016. To be eligible for inclusion in the Draft EIS, all comments must be received prior to the close of the scoping period. NSF will provide additional opportunities for public participation upon publication of the Draft EIS.

ADDRESSES: You may submit comments related to this proposal by either of the following methods:

- *Email to: envcomp-AST-sacpeak@nsf.gov,* with subject line "Sacramento Peak Observatory".

- *Mail to:* Ms. Elizabeth Pentecost, RE: Sacramento Peak Observatory, National Science Foundation, Suite 1045, 4201 Wilson Blvd., Arlington, VA 22230.

FOR FURTHER INFORMATION CONTACT: For further information regarding the EIS process or Section 106 consultation, please contact: Ms. Elizabeth Pentecost, National Science Foundation, Division of Astronomical Sciences, Suite 1045, 4201 Wilson Blvd., Arlington, VA 22230; telephone: (703) 292–4907; email: *epenteco@nsf.gov.*

SUPPLEMENTARY INFORMATION: Sacramento Peak Observatory is located in Sunspot, New Mexico, within the Lincoln National Forest in the Sacramento Mountains. Established by the U.S. Air Force via a memorandum of agreement with the U.S. Forest Service in 1950, the facility was transferred to the National Science Foundation (NSF) in 1976. NSF and the U.S. Forest Service executed a land use agreement (signed in 1980) to formalize this transition and the continued use of the land for the observatory. The primary research facility still in operation at the Sacramento Peak site is the Richard B. Dunn Solar Telescope (DST), currently managed by the National Solar Observatory (NSO). The DST is a high-spatial resolution optical/infrared solar telescope. In addition to its own operations, the Sacramento Peak Observatory supplies water for the nearby Apache Point Observatory (APO).

The NSF Directorate for Mathematical and Physical Sciences, Division of Astronomical Sciences, through a series of academic community-based reviews, has identified the need to divest several facilities from its portfolio in order to deliver the best performance on the emerging and key science technology of the present decade and beyond. In 2012, NSF's Division of Astronomical Sciences (AST's) portfolio review committee, under the category of solar facilities stated that, "AST and NSO should plan for the continued use of the Dunn Solar Telescope (DST) as a world-class scientific observatory, supporting the solar physics community, to within two years of the Advanced Technology Solar Telescope (ATST) [now the Daniel K. Inouye Solar Telescope, DKIST] first light." In 2016, in response to this recommendation, NSF completed a feasibility study to inform and define options for the site's future disposition that would involve significantly decreasing or eliminating NSF funding of the Sacramento Peak Observatory. Alternatives to be evaluated in the EIS will be refined through public input, with preliminary proposed alternatives that include the following:

- Continued NSF investment for science-focused operations (No-Action Alternative)
- Transition to full operations with interested parties for solar astronomy research
- Transition to partial operations with interested parties, and decommissioning or mothballing of facilities not proposed to be used
- Mothballing of facilities limited to basic maintenance
- Deconstruction and site restoration

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including identification of viable alternatives, and guide the process for developing the EIS. At present, NSF has identified the following preliminary resource areas for analysis of potential impacts: Air quality, biological resources, cultural resources, geological resources, solid waste generation, health and safety, socioeconomics, traffic, and groundwater resources. NSF will consult under section 106 of the National Historic Preservation Act and section 7 of the Endangered Species Act in coordination with this EIS process, as appropriate. Federal, state, and local agencies, along with other stakeholders that may be interested or affected by NSF's decision on this proposal are invited to participate in the scoping process and, if eligible, may request to participate as a cooperating agency.

Proposal Information: Information will be posted, throughout the EIS process, at *www.nsf.gov/ast.*

Scoping Meeting: NSF will host one public scoping meeting.

Meeting Date and Location: July 21, 2016, from 6 p.m. to 8 p.m., New Mexico Museum of Space History, 3198 State Route 2001, Alamogordo, NM 88310. Tel: (575) 437–2840.

Comments will be transcribed by a court reporter. Please contact NSF at least one week in advance of the meeting if you would like to request special accommodations (*i.e.,* sign language interpretation, etc.).

Dated: June 24, 2016.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2016–15783 Filed 7–1–16; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–369 and 50–370; NRC–2016–0049]

Duke Energy Carolinas, LLC; McGuire Nuclear Station, Units 1 and 2; Alternative to the Physical Inventory Requirements for Movable In-Core Detectors

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption for Renewed Facility Operating License Nos. NPF–9 and NPF–17, issued to Duke Energy Carolinas, LLC (the licensee) that would allow an alternative to the physical inventory requirements for movable in-core detectors for the McGuire Nuclear Station, Units 1 and 2 (McGuire), located in Mecklenburg County, North Carolina.

DATES: July 5, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0049 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0049. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

The exemption is being withheld from public disclosure pursuant section 2.390 of title 10 of the *Code of Federal Regulations* (10 CFR), because it contains official use only security-related information. A non-sensitive summary of the exemption is included in this notice.

FOR FURTHER INFORMATION CONTACT: G. Edward Miller, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2481, email: *Ed.Miller@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Duke Energy Carolinas, LLC is the holder of Renewed Facility Operating License Nos. NPF–9 and NPF–17, which authorize operation of McGuire. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. The facility consists of two pressurized-water reactors located in Mecklenburg County, North Carolina.

II. Request/Action

The regulation in 10 CFR 74.19, "Recordkeeping," identifies recordkeeping requirements applicable to special nuclear material (SNM), and 10 CFR 74.19(c) requires, in part, that, "each licensee who is authorized to possess special nuclear material, at any one time and site location, in a quantity greater than 350 grams of contained uranium-235, uranium-233, or plutonium, or any combination thereof, shall conduct a physical inventory of all special nuclear material in its possession under license at intervals not to exceed 12 months."

The licensee requested an exemption from certain recordkeeping requirements in 10 CFR 74.19(c). The exemption would allow the licensee to seek relief from the physical inventory requirements only for movable incore nuclear detectors that have been removed from service and stored in a location that is not readily accessible and is subject to security modifications. The purpose of this request for exemption is to allow an alternative to the physical inventory-taking practices for these non-fuel SNM incore detectors.

III. Discussion

Pursuant to 10 CFR 74.7, "Specific exemptions," the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 74 when the exemptions are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

The Exemption Is Authorized by Law

This exemption allows the licensee to have an alternative to the physical inventory requirements of 10 CFR 74.19(c) only for movable incore nuclear detectors that have been removed from service. The NRC staff has determined that granting the licensee's proposed exemption pursuant to 10 CFR 74.7 will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

The Exemption Presents No Undue Risk to Public Health and Safety

The underlying purpose of 10 CFR 74.19(c) is to ensure SNM is properly accounted for, appropriately secured, and that authorities are informed of any theft, diversion, or loss. Based on the information provided, no new accident precursors are created by the description of actions the licensee has provided concerning the physical inventory for the incore nuclear detectors. Thus, the probability of postulated accidents is not increased. Also, the consequences of postulated accidents are not increased. Therefore, there is no undue risk to public health and safety.

The Exemption Is Consistent With the Common Defense and Security

The proposed exemption would allow the licensee to address the physical inventory of the non-fuel SNM. The licensee indicated that the overall alternative approach will continue to meet the intent of the physical inventory requirements of 10 CFR 74.19(c). Therefore, the common defense and security are not impacted by this exemption.

IV. Conclusion

Accordingly, the Commission has determined that pursuant to 10 CFR 74.7, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Therefore, the Commission hereby grants Duke Energy Carolinas, LLC an exemption from the physical inventory requirements of 10 CFR 74.19(c) for McGuire.

Pursuant to 10 CFR 51.32, "Finding of no significant impact," the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment as published in the **Federal Register** on March 8, 2016 (81 FR 12132).

The exemption is effective upon issuance.

Dated at Rockville, Maryland, this 23rd day of June, 2016.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–15868 Filed 7–1–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0127]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to Section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from June 7, 2016, to June 20, 2016. The last biweekly notice was published on June 21, 2016.

DATES: Comments must be filed by August 4, 2016. A request for a hearing must be filed by September 6, 2016.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0127. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lynn Ronewicz, Office of Nuclear

Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1927, email: *lynn.ronewicz@nrc.gov.*

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0127 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0127.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select *"ADAMS Public Documents"* and then select *"Begin Web-based ADAMS Search."* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0127, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies and procedures.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii). If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by September 6, 2016. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by September 6, 2016.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

For further details with respect to these license amendment applications, see the application for amendment, which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

Duke Energy Carolinas, LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: May 5, 2016. A publicly available version is in ADAMS under Accession No. ML16134A068.

Description of amendment request: The amendments would modify Technical Specifications (TSs) by the removal of Note (c), which is no longer applicable from TS Table 3.3.2–1, "Engineered Safety Feature Actuation System Instrumentation," Function 6.f, "Auxiliary Feedwater Pump Suction Transfer on Suction Pressure—Low," and the removal of an expired one-time Note for Required Action to restore Diesel Generator to OPERABLE status for TS 3.8.1, "AC Sources—Operating."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

This LAR [license amendment request] proposes administrative non-technical changes only. These proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configurations of the facility. The proposed changes do not alter or prevent the ability of structures, systems and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits.

Given the above discussion, it is concluded the proposed amendment does not significantly increase the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

This LAR proposes administrative non-technical changes only. The proposed changes will not alter the design requirements of any Structure, System or Component (SSC) or its function during accident conditions. No new or different accidents result from the proposed changes. The changes do not involve a physical alteration of the plant or any changes in methods governing normal plant operation. The changes do not alter assumptions made in the safety analysis.

Given the above discussion, it is concluded the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

This LAR proposes administrative non-technical changes only. The proposed changes do not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not affected by these changes. The proposed changes will not result in plant operation in a configuration outside the design basis. The proposed changes do not adversely affect systems that respond to safely shutdown the plant and to maintain the plant in a safe shutdown condition.

Given the above discussion, it is concluded the proposed amendment does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 526 South Church Street—EC07H, Charlotte, NC 28202.

NRC Branch Chief: Michael T. Markley.

Duke Energy Carolinas, LLC, Docket Nos. 50–269, 50–270, and 50–287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Date of amendment request: February 26, 2016. A publicly-available version is in ADAMS under Accession No. ML16064A020.

Description of amendment request: The amendments would revise Technical Specifications (TSs) for the Oconee Nuclear Station, Units 1, 2, and 3 (Oconee). Specifically, the license amendment request (LAR) would revise TS 3.8.1, "AC [Alternating Current] Sources—Operating," Required Action C.2.2.5, to allow each Keowee Hydroelectric Unit to be taken out of service for up to 55 days on a one-time basis for the purpose of generator stator replacement, subject to the implementation of specified contingency measures outlined in the LAR.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below, with NRC edits in square brackets:

> 1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?
>
> *Response:* No.
>
> This change involves the temporary addition of a 55-day Completion Time for Technical Specification (TS) 3.8.1 Required Action C.2.2.5 associated with restoring compliance with TS Limiting Condition for Operation (LCO) 3.8.1.C. During the time that one Keowee Hydroelectric Unit (KHU) is inoperable for [greater than] 72 hours, a Lee Combustion Turbine (LCT) will be energizing both standby buses, two offsite power sources will be maintained available, and maintenance on electrical distribution systems will not be performed unless necessary. In addition, risk significant systems (Emergency Feedwater System, Protected Service Water System, and Standby Shutdown Facility) will be verified operable (meeting LCO requirements) within 72 hours of entering TS 3.8.1 Condition C (*i.e.*, prior to use of the 55-day Completion Time of Required Action C.2.2.5). The temporary 55-day Completion Time will decrease the likelihood of an unplanned forced shutdown of all three Oconee Units and the potential safety consequences and operational risks associated with that action. Avoiding this risk offsets the risks associated with having a design basis event during the temporary 55-day completion time for having one KHU inoperable.
>
> The temporary addition of the 55-day Completion Time does not involve: (1) A physical alteration to the Oconee Units; (2) the installation of new or different equipment; (3) operating any installed equipment in a new or different manner; or (4) a change to any set points for parameters which initiate protective or mitigation action.
>
> There is no adverse impact on containment integrity, radiological release pathways, fuel design, filtration systems, main steam relief valve set points, or radwaste systems. No new radiological release pathways are created.
>
> The consequences of an event occurring during the temporary 55-day Completion Time are the same as those that would occur during the existing Completion Time. Duke Energy reviewed the Probabilistic Risk Assessment (PRA) to gain additional insights concerning the configuration of [Oconee] with one KHU. The results of the risk analysis show a risk improvement if no maintenance is performed on the SSF, EFW System and AC Power System. The results of the risk analysis show a small risk increase using the average nominal maintenance unavailability values for the SSF, EFW System and AC Power System.
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> By limiting maintenance, the risk results are expected to be between these two extremes (*i.e.*, small risk impact).
>
> Therefore, the probability or consequences of an accident previously evaluated is not significantly increased.
>
> 2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?
>
> *Response:* No.
>
> This change involves the temporary addition of a 55-day Completion Time for TS 3.8.1 Required Action C.2.2.5 associated with restoring compliance with TS LCO 3.8.1. During the time period that one KHU is inoperable, the redundancy requirement for the emergency power source will be fulfilled by an LCT. Compensatory measures previously specified will be in place to minimize electrical power system vulnerabilities.
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> The temporary 55-day Completion Time does not involve a physical effect on the Oconee Units, nor is there any increased risk of an Oconee Unit trip or reactivity excursion. No new failure modes or credible accident scenarios are postulated from this activity.
>
> Therefore, the possibility of a new or different kind of accident from any kind of accident previously evaluated is not created.
>
> 3. Does the proposed amendment involve a significant reduction in a margin of safety?
>
> *Response:* No.
>
> This change involves the temporary addition of a 55-day Completion Time for TS 3.8.1 Required Action C.2.2.5 associated with restoring compliance with TS LCO 3.8.1. During the time period that one KHU is inoperable, the redundancy requirement for the emergency power source will be fulfilled by an LCT. Compensatory measures previously specified will be in place to minimize electrical power system vulnerabilities.
>
> The proposed TS change does not involve: (1) a physical alteration of the Oconee Units; (2) the installation of new or different equipment; (3) operating any installed equipment in a new or different manner; (4) a change to any set points for parameters which initiate protective or mitigation action; or (5) any impact on the fission product barriers or safety limits.
>
> Therefore, this request does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 526 S. Church St.—EC07H, Charlotte, NC 28202.

NRC Branch Chief: Michael T. Markley.

Duke Energy Progress, Inc., Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant, Units 1 and 2 (BSEP), Brunswick County, North Carolina

Duke Energy Carolinas, LLC, Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Duke Energy Progress, Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1 (HNP), Wake County, North Carolina

Duke Energy Carolinas, LLC, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Duke Energy Carolinas, LLC, Docket Nos. 50–269, 50–270, and 50–287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Duke Energy Progress, Inc., Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2 (RNP), Darlington County, South Carolina

Date of amendment request: April 29, 2016. A publicly-available version is in ADAMS under Accession No. ML16120A076.

Description of amendment request: The amendments would (1) consolidate the Emergency Operations Facilities (EOFs) for BSEP, HNP, and RNP with the Duke Energy Progress, Inc. (Duke

Energy) corporate EOF in Charlotte, North Carolina; (2) change the BSEP, HNP, and RNP augmentation times to be consistent with those of the sites currently supported by the Duke Energy corporate EOF; and (3) decrease the frequency of the unannounced augmentation drill at BSEP from twice per year to once per year.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes relocate the BSEP, HNP, and RNP EOFs from their present onsite or near-site locations to the established corporate EOF in Charlotte, North Carolina, changes the required response times for supplementing onsite personnel in response to a radiological emergency, and decreases the frequency of augmentation drills at BSEP. The functions and capabilities of the relocated EOFs will continue to meet the applicable regulatory requirements. It has been evaluated and determined that the change in response time does not significantly affect the ability to supplement the onsite staff. In addition, analysis shows that the onsite staff can acceptably respond to an event for longer than the requested time for augmented staff to arrive. The proposed changes have no effect on normal plant operation or on any accident initiator or precursors, and do not impact the function of plant structures, systems, or components (SSCs). The proposed changes do not alter or prevent the ability of the emergency response organization to perform its intended functions to mitigate the consequences of an accident or event. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes only impact the implementation of the affected stations' emergency plans by relocating their onsite or near-site EOFs to the established corporate EOF in Charlotte, North Carolina, changing the required response time of responders who supplement the onsite staff, and decreasing the frequency of augmentation drills at BSEP. The functions and capabilities of the relocated EOFs will continue to meet the applicable regulatory requirements. It has been evaluated and determined that the change in response time does not significantly affect the ability to supplement the onsite staff. In addition, analysis shows that the onsite staff can acceptably respond to an event for longer than the requested time for augmented staff to arrive. The proposed changes will not change the design function or operation of SSCs. The changes do not impact the accident analysis. The changes do not involve a physical alteration of the plant, a change in the method of plant operation, or new operator actions. The proposed changes do not introduce failure modes that could result in a new accident, and the changes do not alter assumptions made in the safety analysis.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes only impacts the implementation of the affected stations' emergency plans by relocating their onsite or near-site EOFs to the established corporate EOF in Charlotte, North Carolina, changing the required response time of responders who supplement the onsite staff, and decreasing the frequency of augmentation drills at BSEP. The functions and capabilities of the relocated EOFs will continue to meet the applicable regulatory requirements. It has been evaluated and determined that the change in response time does not significantly affect the ability to supplement the onsite staff. In addition, analysis shows that the onsite staff can acceptably respond to an event for longer than the requested time for augmented staff to arrive. Margin of safety is associated with confidence in the ability of the fission product barriers (*i.e.*, fuel cladding, reactor coolant system pressure boundary, and containment structure) to limit the level of radiation dose to the public. The proposed changes are associated with the emergency plans and do not impact operation of the plant or its response to transients or accidents. The changes do not affect the Technical Specifications. The changes do not involve a change in the method of plant operation, and no accident analyses will be affected by the proposed changes. Safety analysis acceptance criteria are not affected. The emergency plans will continue to provide the necessary response staff for emergencies as demonstrated by staffing and functional analyses including the necessary timeliness of performing major tasks for the functional areas of the emergency plans.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 550 South Tyron Street, Mail Code DEC45A, Charlotte, NC 28202.

NRC Acting Branch Chief: Tracy J. Orf.

Duke Energy Progress, Inc., Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2 (HBRSEP2), Darlington County, South Carolina

Date of amendment request: April 24, 2016. A publicly-available version is in ADAMS under Accession No. ML16116A033.

Description of amendment request: The amendment would adopt Technical Specifications Task Force (TSTF) Traveler TSTF–339, Revision 2, "Relocated TS Parameters to COLR." Based on TSTF–339, the proposed amendment would relocate reactor coolant system (RCS)-related cycle-specific parameters and core safety limits from the technical specifications (TSs) to the Core Operating Limits Report (COLR).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The relocation of RCS-related cycle-specific parameter limits from the TS to the COLR proposed by this amendment request does not result in the alteration of the design, material, or construction standards that were applicable prior to the change. The proposed change will not result in the modification of any system interface that would increase the likelihood of an accident since these events are independent of the proposed change. The proposed amendment will not change, degrade, or prevent actions, or alter any assumptions previously made in evaluating the radiological consequences of an accident described in the Updated Final Safety Analysis Report (UFSAR). Therefore, the proposed amendment does not result in an increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

There are no new accident causal mechanisms created as a result of NRC approval of this amendment request. No changes are being made to the facility which would introduce any new accident causal mechanisms. This amendment request does not impact any plant systems that are accident initiators. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in margin of safety?

Response: No.

Implementation of this amendment would not involve a significant reduction in the margin of safety. Previously approved methodologies will continue to be used in the determination of cycle-specific core operating limits that are present in the COLR. Additionally, previously approved RCS minimum total flow rates for HBRSEP2 are retained in the TS to assure that lower flow rates will not be used without prior NRC approval. Based on the above, it is concluded that the proposed license amendment request does not impact any safety margins and will not result in a reduction in margin with respect to plant safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 550 South Tyron Street, Mail Code DEC45A, Charlotte, NC 28202.

NRC Acting Branch Chief: Robert G. Schaaf.

Florida Power & Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Nuclear Generating, Unit Nos. 3 and 4, Miami-Dade County, Florida

Date of amendment request: April 4, 2016. A publicly-available version is in ADAMS under Accession No. ML16110A266.

Description of amendment request: The amendments would revise the Technical Specifications (TS) requirements for snubbers. The licensee proposed to revise the TSs to conform to the licensee's Snubber Testing Program. The proposed changes include additions to, deletions from, and conforming administrative changes to the TSs.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes would revise TS SR [Surveillance Requirement] 4.7.6 to conform the TS to the revised surveillance program for snubbers. Snubber examination, testing and service life monitoring will continue to meet the requirements of 10 CFR 50.55a(g).

Snubber examination, testing and service life monitoring is not an initiator of any accident previously evaluated. Therefore, the probability of an accident previously evaluated is not significantly increased.

Snubbers will continue to be demonstrated OPERABLE by performance of a program for examination, testing and service life monitoring in compliance with 10 CFR 50.55a or authorized alternatives. The proposed change to the TS 3.7.6 Action for inoperable snubbers is administrative in nature and is required for consistency with the proposed change to TS SR 4.7.6. The proposed change does not adversely affect plant operations, design functions or analyses that verify the capability of systems, structures, and components to perform their design functions therefore, the consequences of accidents previously evaluated are not significantly increased.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not involve any physical alteration of plant equipment. The proposed changes do not alter the method by which any safety-related system performs its function. As such, no new or different types of equipment will be installed, and the basic operation of installed equipment is unchanged. The methods governing plant operation and testing remain consistent with current safety analysis assumptions.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes ensure snubber examination, testing and service life monitoring will continue to meet the requirements of 10 CFR 50.55a(g). Snubbers will continue to be demonstrated OPERABLE by performance of a program for examination, testing and service life monitoring in compliance with 10 CFR 50.55a or authorized alternatives.

The proposed change to the TS 3.7.6 Action for inoperable snubbers is administrative in nature and is required for consistency with the proposed change to TS SR 4.7.6.

Therefore, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William S. Blair, Managing Attorney—Nuclear, Florida Power & Light Company, 700 Universe Blvd., MS LAW/JB, Juno Beach, FL 33408–0420.

NRC Branch Chief: Benjamin G. Beasley.

South Carolina Electric and Gas Company and South Carolina Public Service Authority, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: May 16, 2016. A publicly-available version is in ADAMS under Accession No. ML16137A171.

Description of amendment request: The proposed changes, if approved for the VCSNS, involve departures from incorporated plant-specific Tier 2 Updated Final Safety Analysis Report (UFSAR) information and conforming changes to the combined license Appendix C, as well as conforming changes to the plant-specific Tier 1 information, to ensure that the design bases Tier 2 information conforms with the originally certified design. The licensee stated in its application that the changes are editorial, and with one exception, bring the plant-specific Tier 1 and Combined License (COL) Appendix C into alignment with the information contained in plant-specific Tier 2. In addition, the licensee requested a change to COL License Condition 2.D(12)(f)1 to correct a reference to a seismic interaction review discussed in the AP1000 design certification document, Revision 19, Section 3.7.5.3.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed consistency and editorial COL Appendix C (and plant-specific Tier 1) and involved Tier 2 changes, along with one COL paragraph 2.D change, do not involve a technical change, (*e.g.,* there is no design parameter or requirement, calculation, analysis, function or qualification change). No structure, system, component design or function would be affected. No design or safety analysis would be affected. The proposed changes do not affect any accident initiating event or component failure, thus the probabilities of the accidents previously evaluated are not affected. No function used to mitigate a radioactive material release and no radioactive material release source term is involved, thus the radiological releases in the accident analyses are not affected.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of

accident from any accident previously evaluated?

Response: No.

The proposed consistency and editorial COL Appendix C (and plant-specific Tier 1) and involved Tier 2 changes, along with one COL paragraph 2.D change, would not affect the design or function of any structure, system, component (SSC), but will instead provide consistency between the SSC designs and functions currently presented in the UFSAR and the Tier 1 information. The proposed changes would not introduce a new failure mode, fault or sequence of events that could result in a radioactive material release. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed consistency and editorial COL Appendix C (and plant-specific Tier 1) and involved Tier 2 update, along with one COL paragraph 2.D change, is non-technical, thus would not affect any design parameter, function or analysis. There would be no change to an existing design basis, design function, regulatory criterion, or analysis. No safety analysis or design basis acceptance limit/criterion is involved. Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 1111 Pennsylvania Avenue NW., Washington, DC 20004–2514.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

South Carolina Electric and Gas Company, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina

Date of amendment request: May 12, 2016. A publicly-available version is available in ADAMS under Accession No. ML16133A382.

Description of amendment request: The proposed changes, if approved for the VCSNS, involve departures from incorporated plant-specific Tier 2 Updated Final Safety Analysis Report (UFSAR) information and changes to the combined license Appendix A Technical Specifications to ensure that the listed minimum volume of the passive core cooling system core makeup tanks are aligned with the current inspections tests analyses and acceptance criteria and the relevant safety analysis.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed activity would revise the minimum CMT [Core Makeup Tank] volume in the COL [combined operating license] Appendix A (Technical Specifications) and UFSAR information to be consistent with the plant-specific Tier 1 and COL Appendix C requirements. Because the new minimum volume is bounded by the current analyses, the proposed activity does not alter the design of an accident initiating component or system. Thus, the probabilities of an accident previously evaluated are not affected. The proposed activity does not involve other safety-related equipment or radioactive material barriers. Thus, the proposed activity does not affect an accident mitigation function.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed activity would revise the minimum CMT volume in the COL Appendix A (Technical Specifications) and UFSAR information to be consistent with the plant-specific Tier 1 and COL Appendix C requirements. No results or conclusions of any design or safety analyses are affected. No system or design function or equipment qualification is affected by the changes. The changes do not result in a new failure mode, malfunction or sequence of events that could affect safety or safety-related equipment. This activity does not allow for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that results in significant fuel cladding failures.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed activity would revise the minimum CMT volume in the COL Appendix A (Technical Specifications) and UFSAR information to be consistent with the plant-specific Tier 1 and COL Appendix C requirements. No results or conclusions of any design or safety analyses are affected. No system design function or equipment is altered by this activity, and the proposed changes do not alter any design code, safety classification, or design margin. No safety analysis or design basis limit is involved with the requested change, and consequently, no margin of safety is reduced.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 1111 Pennsylvania Avenue NW., Washington, DC 20004–2514.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant (VEGP), Units 3 and 4, Burke County, Georgia

Date of amendment request: May 18, 2016. A publicly-available version is in ADAMS under Accession No. ML16139A796.

Description of amendment request: The amendment request proposes changes to the technical specifications (TS) and Updated Final Safety Analysis Report (UFSAR) in the form of departures from the incorporated plant-specific Design Control Document Tier 2 information. Specifically, the proposed departures consist of changes to the TS and UFSAR to revise the minimum volume of the passive core cooling system core makeup tanks.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed activity would revise the minimum CMT [core makeup tank] volume in the COL [combined operating license] Appendix A (Technical Specifications) and UFSAR information to be consistent with the plant-specific Tier 1 and COL Appendix C requirements. Because the new minimum volume is bounded by the current analyses, the proposed activity does not alter the design of an accident initiating component or system. Thus, the probabilities of an accident previously evaluated are not affected. The proposed activity does not involve other safety-related equipment or radioactive material barriers. Thus, the proposed activity does not affect an accident mitigation function.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed activity would revise the minimum CMT volume in the COL Appendix A (Technical Specifications) and UFSAR information to be consistent with the plant-specific Tier 1 and COL Appendix C requirements. No results or conclusions of any design or safety analyses are affected. No system or design function or equipment qualification is affected by the changes. The changes do not result in a new failure mode, malfunction or sequence of events that could affect safety or safety-related equipment. This activity does not allow for a new fission product release path, result in a new fission product barrier failure mode, or create a new sequence of events that results in significant fuel cladding failures.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed activity would revise the minimum CMT volume in the COL Appendix A (Technical Specifications) and UFSAR information to be consistent with the plant-specific Tier 1 and COL Appendix C requirements. No results or conclusions of any design or safety analyses are affected. No system design function or equipment is altered by this activity, and the proposed changes do not alter any design code, safety classification, or design margin. No safety analysis or design basis limit is involved with the requested change, and consequently, no margin of safety is reduced. Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

NRC Acting Branch Chief: Jennifer Dixon-Herrity.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendments.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action, see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, safety evaluation, and/or environmental assessment, as indicated. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

Duke Energy Carolinas, LLC, Docket Nos. 50–269, 50–270, and 50–287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Date of amendment request: July 17, 2015.

Brief description of amendments: The amendments correct a usage problem with recently issued Amendment Nos. 382, 384, and 383 (ADAMS Accession No. ML13231A013), which precludes Oconee Nuclear Station Technical Specification (TS) 3.8.1, "AC [Alternating Current] Sources—Operating," Condition H, from being used as planned. The change revises the note to TS 3.8.1, Required Actions L.1, L.2, and L.3 to delete the 12-hour time limitation when the second Keowee Hydroelectric Unit (KHU) is made inoperable for the purpose of restoring the KHU undergoing maintenance to OPERABLE status. Deletion of the 12-hour time limitation allows the use of the full 60-hour Completion Time of Required Action H.2 when the unit(s) have been in Condition C for greater than 72 hours, and both units are made inoperable for the purpose of restoring the KHU undergoing maintenance to OPERABLE status.

Date of issuance: June 6, 2016.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 400 (Unit 1), 402 (Unit 2), and 401 (Unit 3). A publicly-available version is in ADAMS under Accession No. ML16138A332; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–38, DPR–47, and DPR–55: The amendments revised the Renewed Facility Operating Licenses and TSs.

Date of initial notice in ***Federal Register***: November 10, 2015 (80 FR 69710).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 6, 2016.

No significant hazards consideration comments received: No.

Entergy Nuclear Operations, Inc., Docket No. 50–293, Pilgrim Nuclear Power Station (PNPS), Plymouth County, Massachusetts

Date of amendment request: July 15, 2015.

Brief description of amendment: The amendment approved the revised schedule for full implementation of the Cyber Security Plan (CSP) for Milestone 8 by extending the date from June 30, 2016, to December 15, 2017, and revised paragraphs 3.B and 3.G of Facility Operating License No. DPR–35 for PNPS to incorporate the revised CSP implementation schedule.

Date of issuance: June 6, 2016.

Effective date: As of the date of issuance and shall be implemented within 30 days.

Amendment No.: 244. A publicly-available version is in ADAMS under Accession No. ML16082A460; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. DPR–35: The amendment revised the Renewed Facility Operating License.

Date of initial notice in ***Federal Register***: October 27, 2015 (80 FR 65812).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated June 6, 2016.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, Docket Nos. 50–334 and 50–412, Beaver Valley Power Station (BVPS), Unit Nos. 1 and 2, Beaver County, Pennsylvania Docket No. 50–346, Davis-Besse Nuclear Power Station (DBNPS), Unit No. 1, Ottawa County, Ohio

Date of application for amendments: November 19, 2015, as supplemented by letter dated March 22, 2016.

Brief description of amendments: The amendments changed the BVPS and DBNPS Technical Specifications (TSs). Specifically, the license amendments revised TS 5.3.1, "Unit Staff Qualifications," by incorporating an exception to American National Standards Institute (ANSI) Standard N18.1–1971, "Selection and Training of Nuclear Power Plant Personnel," such that licensed operators are only required to comply with the requirements of 10 CFR part 55, "Operators' Licenses."

Date of issuance: June 7, 2016.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment Nos.: 297 and 185 for BVPS, Units 1 and 2, and 292 for DBNPS, Unit 1. A publicly-available version is in ADAMS under Accession No. ML16040A084. Documents related to these amendments are listed in the Safety Evaluation (SE) enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–66, NPF–73, and NPF–3: The amendments revised the TSs and Renewed Facility Operating Licenses.

Date of initial notice in ***Federal Register***: January 19, 2016 (81 FR 2918). The supplemental letter dated March 22, 2016, contained clarifying information and did not change the NRC staff's initial proposed finding of no significant hazards consideration.

The Commission's related evaluation of the amendments is contained in an SE dated June 7, 2016.

No significant hazards consideration comments received: No.

Luminant Generation Company LLC, Docket Nos. 50–445 and 50–446, Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2 (CPNPP), Somervell County, Texas

Date of amendment request: June 30, 2015, as supplemented by letters dated January 27, 2016, and March 3, 2016.

Brief description of amendments: The amendments revised the current emergency action level scheme for CPNPP to a scheme based on Nuclear Energy Institute (NEI) 99–01, Revision 6, "Development of Emergency Action Levels for Non-Passive Reactors," November 2012.

Date of issuance: June 14, 2016.

Effective date: As of the date of issuance and shall be implemented within 270 days from the date of issuance.

Amendment Nos.: 166 (Unit 1) and 166 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML16137A056; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Facility Operating Licenses to authorize revision to the CPNPP Emergency Plan.

Date of initial notice in ***Federal Register***: August 14, 2015 (80 FR 48923), and corrected on August 20, 2015 (80 FR 50663). The supplemental letters dated January 27, 2016, and March 3, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 14, 2016.

No significant hazards consideration comments received: No.

Northern States Power Company—Minnesota, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant, Units 1 and 2, Goodhue County, Minnesota

Date of amendment request: June 29, 2015, as supplemented by letters dated December 30, 2015; January 25, 2016; March 31, 2016; and April 14, 2016.

Brief description of amendments: The amendments revised surveillance requirements (SRs) related to gas accumulation for the emergency core cooling system and added new SRs related to gas accumulation for the residual heat removal and containment spray systems, consistent with NRC-approved Technical Specifications Task Force (TSTF) Standard Technical Specifications Change Traveler TSTF–523, Revision 2, "Generic Letter 2008–01, Managing Gas Accumulation."

Date of issuance: June 16, 2016.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 217 (Unit 1) and 205 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML16133A406; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–42 and DPR–60: The amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: October 13, 2015 (80 FR 61484). The supplemental letters dated December 30, 2015; January 25, 2016; March 31, 2016; and April 14, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 16, 2016.

No significant hazards consideration comments received: No.

Omaha Public Power District, Docket No. 50–285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of amendment request: September 11, 2015.

Brief description of amendment: The amendment revised the Technical Specifications (TSs) to provide a short Completion Time to restore an inoperable system for conditions under which the existing TSs require a plant shutdown. The amendment is consistent with NRC-approved Technical Specifications Task Force (TSTF) Traveler TSTF–426, Revision 5, "Revise or Add Actions to Preclude Entry into LCO [Limiting Condition for Operation] 3.0.3—RITSTF [Risk-Informed TSTF] Initiatives 6b & 6c," with certain plant-specific administrative variations.

Date of issuance: June 8, 2016.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment No.: 288. A publicly-available version is in ADAMS under Accession No. ML16139A804; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–40: The amendment revised the Renewed Facility Operating License and TSs.

Date of initial notice in ***Federal Register***: November 24, 2015 (80 FR 73239).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated June 8, 2016.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–424 and 50–425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: July 18, 2014, as supplemented by letters dated February 27, 2015, and May 2, 2016.

Brief description of amendments: The amendments revised 22 Technical Specifications (TSs) by adopting multiple previously NRC-approved Technical Specifications Task Force (TSTF) Travelers. One proposed change is not included in this license amendment and will be addressed by further correspondence. Southern Nuclear Operating Company, Inc. (SNC) stated that these TSTF Travelers are generic changes chosen to increase the consistency between the Vogtle Electric Generating Plant TSs, the Improved Standard Technical Specifications for Westinghouse plants (NUREG–1431), and the TSs of the other plants in the SNC fleet.

Date of issuance: June 9, 2016.

Effective date: As of the date of issuance and shall be implemented within 120 days of issuance.

Amendment Nos.: 180 (Unit 1) and 161 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML15132A569; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–68 and NPF–81: Amendments revised the Facility Operating Licenses and TSs.

Date of initial notice in ***Federal Register***: March 3, 2015 (80 FR 11480). The supplemental letters dated February 27, 2015, and May 2, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposal no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 9, 2016.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Date of amendment request: April 13, 2015, as supplemented by letters dated September 17, 2015, and April 13, 2016.

Brief description of amendments: The amendments consist of changes to the Technical Specifications consistent with the NRC-approved Technical Specification Task Force Improved Standard Technical Specifications Change Traveler-432, Revision 1, "Change in Technical Specifications End States (WCAP–16294)," dated November 29, 2010.

Date of issuance: June 10, 2016.

Effective date: As of its date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 202 (Unit 1) and 198 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML15289A227; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–2 and NPF–8: The amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: May 26, 2015 (80 FR 30102). The supplemental letters dated September 17, 2015, and April 13, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated June 10, 2016.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 22nd day of June 2016.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–15659 Filed 7–1–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–390; NRC–2016–0131]

Tennessee Valley Authority Watts Bar Nuclear Plant, Unit 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of an amendment to Facility Operating License No. NFP–90, issued February 7, 1996, and held by the Tennessee Valley Authority (TVA, the licensee) for the operation of Watts Bar Nuclear Plant (WBN), Unit 1. The proposed amendment would revise Technical Specification (TS) 4.2.1, "Fuel Assemblies"; TS 3.5.1 "Accumulators"; Surveillance Requirement (SR) 3.5.1.4; TS 3.5.4, "Refueling Water Storage Tank"; and SR 3.5.4.3, to increase the maximum number of tritium producing burnable absorber rods (TPBARs) and to delete outdated information related to the tritium production program. The NRC staff is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) associated with the proposed license amendment.

DATES: The Environmental assessment referenced in this document is available on July 5, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0131 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site*: Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0131. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the AVAILABILITY OF DOCUMENTS section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Robert Schaaf, Office of Nuclear Reactor Regulation, Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6020, email: *Robert.Schaaf@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of an amendment to Facility Operating License No. NFP–90, issued to TVA for operation of the WBN, Unit 1, located in Rhea County, Tennessee. The proposed action would allow TVA to make changes to the TSs to increase the maximum number of TPBARs that can be irradiated, per cycle, in the WBN, Unit 1 core from 704 to 1,792. In accordance with National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*) and section 51.21 of title 10 of the *Code of Federal Regulations* (10 CFR), the NRC performed an EA. Based on the following EA, the NRC has concluded that the proposed actions will have no significant environmental impact, and is issuing a FONSI.

The U.S. Department of Energy (DOE) and TVA will cooperate in a program to produce tritium for the National Security Stockpile by irradiating TPBARs in the WBN, Unit 1 reactor core. Tritium is produced when the neutrons produced by nuclear fission in the core are absorbed by the lithium target material of the TPBAR. A solid zirconium metal cladding covering the TPBAR (called a "getter") captures the tritium produced. Most of the tritium is contained within the TPBAR, however, some tritium permeates through the TPBAR cladding and is released into the reactor coolant system.

By letter dated September 23, 2002, the NRC approved Amendment No. 40 to Facility Operating License No. NPF–90 for WBN, Unit 1. The amendment allowed TVA to irradiate up to 2,304 TPBARs in the WBN, Unit 1 reactor core each fuel cycle. This approval was based, in part, on NRC's approval of DOE topical report "Tritium Production Core Topical Report," NPD–98–181, dated July 30, 1998, revised February 10, 1999, which assumed that an average of 1 Curie (Ci) per year of tritium would be released from each TPBAR into the reactor coolant, thereby establishing a design basis source term for impact evaluation of 2,304 Ci/year attributable to TPBARs.

Because of issues related to the reactor coolant boron concentration, and a higher than expected permeability of tritium from the TPBARs, the TVA requested, and the NRC approved, Amendment 48 to the WBN, Unit 1 operating license, issued October 8, 2003. Amendment 48 limited the number of TPBARs to be irradiated in WBN, Unit 1, fuel cycle number 6 to 240 TPBARs. Subsequently, a series of amendments limiting the number of TPBARs allowed to be loaded into the WBN, Unit 1, reactor core were reviewed and approved by the NRC. Currently, Amendment 77, issued May 4, 2009, limits the maximum loading of the WBN, Unit 1 reactor core to 704 TPBARs. This limit reflects the average tritium permeation of approximately 3.27 Ci/TPBAR/year experienced during TPBAR operations in fuel cycles 6 through 8, which limits the number of TPBARs that could be loaded without exceeding the original design basis source term of 2,304 Ci/year attributable to TPBARs.

The current request to allow core loadings up to 1,792 TPBARs will support TVA's ability to meet the DOE agreement and national security stockpile needs.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would revise TS 4.2.1, "Fuel Assemblies"; TS 3.5.1 "Accumulators"; SR 3.5.1.4; TS 3.5.4, "Refueling Water Storage Tank"; and SR 3.5.4.3, to increase the maximum number of TPBARs and to delete outdated information related to the tritium production program.

The proposed action is in accordance with the licensee's application dated March 31, 2015, as supplemented by letters dated April 28, May 27, June 15, September 14, September 25, November 30, December 22, December 29, 2015, February 22, and March 31, 2016.

Need for the Proposed Action

The proposed action would allow WBN, Unit 1, to support the DOE, National Nuclear Security Administration, national security stockpile needs in accordance with Public Law (PL) 106–65. Section 3134 of PL 106–65 directs the Secretary of Energy to produce new tritium at TVA's Watts Bar power plant.

Environmental Impacts of the Proposed Action

The radiological and non-radiological impacts on the environment that may result from the proposed action are summarized below.

Non-Radiological Impacts

The proposed action would not change the types and amounts of any non-radiological liquid or gaseous effluents that may be released offsite. There would also be no physical changes to any structures or land use within the WBN site, and the proposed action would not impact air quality, water resources, or aquatic resources. In addition, the proposed action would not result in any socioeconomic or environmental justice impacts or impacts to historic and cultural resources.

Therefore, there would be no significant non-radiological environmental impacts to any resource or any irreversible and irretrievable commitments of resources.

Radiological Impacts

Radioactive Gaseous and Liquid Effluents and Solid Waste

The WBN, Unit 1, includes waste treatment systems to collect, process, recycle, and dispose of gaseous, liquid, and solid wastes that contain radioactive material in a safe and controlled manner within NRC and U.S. Environmental Protection Agency's radiation safety standards. Implementation of the proposed action would result in an increase in the maximum number of TPBARs that can be irradiated, per cycle, in the WBN, Unit 1 core, from 704 to 1,792. This would affect the quantities of radioactive material generated during plant operations as some tritium permeates through the TPBAR cladding and is released into the reactor coolant system. The historical average observed TPBAR tritium permeation rate through cycle 12 is 3.4 Ci/TPBAR/year, with the maximum observed permeation rate being approximately 4.8 Ci/TPBAR/year. For the purposes of assessing the environmental impacts and regulatory compliance of its license amendment request, TVA assumed a core load of 1,900 TPBARs with a permeation rate of 5.0 Ci/TPBAR/year of tritium, which is a conservative source term that bounds the observed and maximum TPBAR tritium permeation rate. While the quantity of tritium generated during plant operations will increase under the proposed action, TVA has stated that the current radioactive waste treatment systems will be able to handle that increase.

Radioactive Gaseous Effluents

The WBN, Unit 1, maintains a gaseous waste management system (GWMS) that is designed to process and control the release of radioactive gaseous effluents into the environment in accordance with the requirements of 10 CFR 20.1301, "Dose limits for individual members of the public," and to ensure consistency with the as low as is reasonably achievable (ALARA) dose objectives set forth in appendix I to 10 CFR part 50.

As stated above relative to TVA's license amendment request, TVA assumed a core load of 1,900 TPBARs with a permeation rate of 5.0 Ci/TPBAR/year of tritium, which is a conservative source term that bounds the observed and maximum TPBAR tritium permeation rate. For its analysis of radioactive gaseous effluents, TVA assumed that 10 percent of the tritium is released as gaseous effluent.

To determine whether the gaseous effluents would fall within the requirements of 10 CFR 20.1301, TVA calculated the sum of the ratios of each isotope concentration (C) to its corresponding gaseous Effluent Concentration Limit (ECL, as listed in 10 CFR part 20, appendix B, Table 2, Column 1). Consistent with the requirements of 10 CFR 20.1302(b)(2)(i), a C/ECL sum of less than 1.0 indicates that the annual average effluent release is within the limits of 10 CFR 20.1301. Tables 8 and 9 of the license amendment request demonstrate that TVA's calculated C/ECL sums for gaseous effluent releases from an assumed core load of 1,900 TPBARs for containment purge without filtration would be 3.15×10^{-1} and would be 2.73×10^{-1} with continuous filtration. Both numbers are within the maximum C/ECL limit of 1.0.

To determine whether the gaseous effluents are consistent with the ALARA dose objectives set forth in appendix I to 10 CFR part 50, TVA calculated bounding public doses from the applicable plant effluent dose pathways with the tritium release attributable to TPBAR permeability. These doses were based on an assumed core load of 1,900 TPBARs and the methods and assumptions in the current WBN Offsite Dose Calculation Manual (ODCM), (documented in the "Watts Bar Nuclear Plant Unit 1, Annual Radioactive Effluent Release Report—2014"). TVA calculated that the Whole Body dose to a Maximally Exposed Individual would be 0.55 millirem (mrem) (0.0055 millisievert (mSv)), which is much less than the Whole Body dose criterion in appendix I to 10 CFR part 50 of 5.00 mrem (0.05 mSv). TVA also calculated that the Organ Dose (Bone) to the Maximally Exposed Individual would be 10.6 mrem (0.106 mSv), which is less than the Organ dose criterion in Appendix I to 10 CFR part 50 of 15.00 mrem (0.15 mSv).

The NRC staff finds that the TVA's analyses have demonstrated that WBN, Unit 1, can be operated with the proposed maximum core loading of 1,792 TPBARs and that the current GWMS can maintain the gaseous effluents within the Effluent Concentration Limits listed in 10 CFR part 20, appendix B to meet the dose limit requirements to members of the public in 10 CFR 20.1301, as well as maintain doses to the public ALARA dose objectives set forth in appendix I to 10 CFR part 50. Therefore, the NRC staff concludes that there would not be a significant radiological impact from gaseous effluents under the proposed action.

Radioactive Liquid Effluents

The WBN, Unit 1 liquid radioactive waste system (LRWS) is used to collect and process radioactive liquid wastes to reduce radioactivity and chemical concentrations to levels acceptable for discharge to the environment. The LRWS maintains sufficient processing capability so that liquid waste may be discharged to the environment below the regulatory limits of 10 CFR 20.1301 and consistent with the ALARA dose objectives in appendix I to 10 CFR part 50. The WBN, Unit 1 has three large tanks in the LRWS, which includes a Tritiated Water Storage Tank with a capacity of 500,000 gallons. This tank supports managing large volume/high tritium concentrations in the reactor coolant system. These tanks can be used for liquid effluent holdup, dilution, and timing of releases to ensure that regulatory requirements are met. Release of radioactive liquids from the LRWS only occurs after laboratory analysis of the tank contents. If the activity is found to be above ODCM limits, the liquid waste streams are returned to the system for further processing by a mobile demineralizer. If the activity is found to be below the ODCM limits, the liquid waste stream is pumped to a discharge pipe where it is monitored for radiation levels and flowrate before it enters the Cooling Tower Blowdown line, where it can be ultimately discharged into the Tennessee River.

As previously described, TVA assumed a core load of 1,900 TPBARs with a permeation rate of 5.0 Ci/TPBAR/year of tritium, which is a conservative source term that bounds the observed and maximum TPBAR tritium permeation rate. For its analysis of radioactive liquid effluents, TVA assumed that 90 percent of the tritium is released as liquid effluent.

To determine whether the liquid effluents are within the requirements of 10 CFR 20.1301, TVA calculated the sum of the ratios of each isotope concentration (C) to its corresponding liquid Effluent Concentration Limit (ECL as listed in 10 CFR part 20, appendix B, Table 2, Column 2). Consistent with the requirements of 10 CFR 20.1302(b)(2)(i), a C/ECL sum of less than 1.0 indicates that the annual average effluent release is within the limits of 10 CFR 20.1301. Tables 5 through 7 of the license amendment request supplement dated March 31, 2016, show TVA's calculated C/ECL sums for liquid effluent releases from an assumed core load of 1,900 TPBARs. Table 5 indicates that extended effluent releases, without processing the liquid radioactive waste streams through the mobile demineralizer or allowing for sufficient dilution of the radioactive waste stream, would not meet the regulatory requirements of 10 CFR 20.1301. The calculated C/ECL is 3.37, which is greater than the maximum allowable C/ECL of 1.0. To ensure that the effluent concentration limits of 10 CFR 20.1301 are met, TVA has revised Section 11.2.6.5 of the Final Safety Analysis Report to include the statement that "No untreated wastes are released unless they are below the Lower Limit of Detection." Table 6 of the license amendment request demonstrates that TVA's calculated C/ECL sum for liquid effluent releases processed through the mobile demineralizer would be 5.7×10^{-1}. Table 7 demonstrates that TVA's calculated C/ECL for liquid effluents not processed through the mobile demineralizer, but sufficiently diluted before release, would be 5.8×10^{-1}. Both numbers are within the maximum C/ECL limit of 1.0.

To determine whether the liquid effluents are consistent with the ALARA dose objectives set forth in appendix I to 10 CFR part 50, TVA calculated bounding public doses from the applicable plant effluent dose pathways with the tritium release attributable to TPBAR permeability. These doses were based on an assumed core load of 1,900 TPBARs and the methods and assumptions in the current ODCM. TVA calculated that the Whole Body dose to a Maximally Exposed Individual from liquid effluents would be 0.43 mrem (0.0043 mSv), which is much less than the Whole Body dose criterion in appendix I to 10 CFR part 50 of 3.00 mrem (0.03 mSv). TVA also calculated that the Organ Dose (Liver) to the Maximally Exposed Individual from liquid effluents would be 0.57 mrem (0.0057 mSv), which is less than the Organ dose criterion in appendix I to 10 CFR part 50 of 10.00 mrem (0.15 mSv).

The NRC staff finds that the TVA analyses have demonstrated that WBN, Unit 1, can be operated with the proposed core loading of 1,792 TPBARs, and that with processing of the liquid radioactive waste streams through the demineralizer, or allowing for proper dilution of the liquid radioactive waste streams, the current LRWS can maintain the liquid effluents within the Effluent Concentration Limits listed in 10 CFR part 20, appendix B. Specifically, doses from liquid effluents would meet the requirements regarding members of the public in 10 CFR 20.1301 as well as maintain the public ALARA dose objectives set forth in appendix I to 10 CFR part 50. Therefore, the NRC staff concludes that there would not be a significant radiological impact from gaseous effluents under the proposed action.

Solid Radioactive Wastes

Solid radioactive wastes generated by nuclear power plant operations at WBN, Unit 1, are processed, packaged, and stored until they are shipped offsite to a vendor for further processing or to a licensed facility for permanent disposal, or both. The storage areas have restricted access and shielding to reduce radiation rates to plant workers. Solid radioactive wastes are packaged and transported in compliance with NRC's regulations in 10 CFR parts 61, "Licensing Requirements for Land Disposal of Radioactive Waste," and 71, "Packaging and Transportation of Radioactive Material," and the U.S. Department of Transportation regulations in 49 CFR parts 170 through 179; and to maintain the dose limits of 10 CFR 20.1201, 10 CFR 20.1301, and appendix I to 10 CFR part 50.

Implementation of the proposed action would be expected to increase the activity and volume of solid radioactive waste due to the irradiation of the TPBAR base plates and thimble plugs, which remain after TPBAR consolidation activities. TVA will consolidate and temporarily store these items on-site, and offsite shipment and ultimate disposal would be conducted in accordance with agreements between TVA and DOE. The disposal volume of the TPBAR base plates and thimble plugs is estimated to be 33.3 cubic feet per year. This additional volume represents a slight increase in the WBN, Unit 1, annual estimated solid waste generation from 32,820 cubic feet per year to 32,853 cubic feet per year. This projected increase in volume can be handled by the existing equipment and plant procedures that control radioactive solid waste handling without modification. The estimated increase in activity inventory attributable to the handling of the TPBAR base plates and thimble plugs ranges from approximately 1,800 Ci/yr to 5,530 Ci/yr. While there would be increased activity associated with implementation of the proposed action, the existing equipment and plant procedures that control radioactive solid waste handling will continue to be used to maintain exposures to plant personnel within the dose limits of 10 CFR 20.1201, 10 CFR 20.1301, and 10 CFR part 50, appendix I. Based on the above, the NRC staff concludes that there would not be a significant radiological impact from solid radioactive waste management under the proposed action.

Spent Fuel Generation and Storage

The number of spent fuel bundles would be expected to increase by approximately four per cycle with implementation of the proposed action. WBN, Unit 1, currently stores spent fuel in spent fuel pools on site, and under 10 CFR 72.210, TVA holds a general license authorizing the operation of an independent spent fuel storage installation (ISFSI) at the Watts Bar site. TVA has notified NRC of its intent to construct an ISFSI under the general license. There will be adequate spent fuel storage available on-site, therefore, the NRC staff concludes that there would not be a significant radiological impact from spent fuel generation and storage under the proposed action.

Occupational Radiation Doses

At WBN, Unit 1, TVA maintains a radiation protection program to monitor radiation levels throughout the nuclear power plant to establish appropriate work controls, training, temporary shielding, and protective equipment requirements so that worker doses will remain within the dose limits of 10 CFR part 20, subpart C, "Occupational Dose Limits." Implementation of the proposed action would affect the quantities of radioactive material generated during plant operations since some tritium permeates through the TPBAR cladding and is released into the reactor coolant system, as previously described. Separate from the environmental review for this EA, the NRC staff is evaluating the licensee's technical and safety analyses provided in TVA's license amendment request to ensure the licensee continues to meet NRC regulatory requirements for occupational dose. The results of the NRC staff's safety review and conclusion will be documented in a safety evaluation that will be made publicly available following issuance of the EA. If the NRC staff concludes in the safety evaluation that the requested increase in the maximum number of TPBARs that can be irradiated, per cycle, in the WBN, Unit 1, core from 704 to 1,792 continues to comply with NRC regulations for occupational dose, then granting the proposed license amendment will not have a significant radiological impact to workers.

Design-Basis Accidents

Design-basis accidents are evaluated by both TVA and the NRC staff to ensure that WBN, Unit 1, can withstand the spectrum of postulated accidents without undue hazard to public health and safety and ensure the protection of the environment.

Separate from the environmental review for this EA, the NRC staff is evaluating the licensee's technical and safety analyses provided in the proposed license amendment to ensure the licensee continues to meet the NRC regulatory requirements for safe operation. The results of the NRC staff's safety review and conclusion will be documented in a safety evaluation that will be made publicly available following issuance of the EA. If the NRC staff concludes in the safety evaluation that the requested increase in the maximum number of TPBARs that can be irradiated, per cycle, in the WBN, Unit 1, core continues to comply with NRC regulations, and there is reasonable assurance that public health and safety will not be endangered, then granting the proposed license amendment will not have a significant environmental impact.

Radiological Impacts Summary

Based on the radiological evaluations associated with this EA, with the exception of the impacts associated with occupational dose and design-basis accidents, which the NRC staff are evaluating separately, implementation of the proposed action would not result in any significant radiological impacts. If the NRC staff concludes in its safety evaluation that the requested increase in the maximum number of TPBARs that can be irradiated, per cycle, in the WBN, Unit 1, core continues to comply with the NRC's regulations, and there is reasonable assurance that public health and safety will not be endangered, then granting the proposed license amendment will not have a significant radiological impact to workers or the environment.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (*i.e.*, the "no-action" alternative). Denial of the license amendment request would result in no change in current environmental impacts.

Alternative Use of Resources

This action does not involve the use of any different resources not previously considered in NUREG–0498, "Final Environmental Statement Related to

Operation of Watts Bar Nuclear Plant, Units 1 and 2," and NUREG–0498, Supplement 1.

Agencies and Persons Consulted

In accordance with its stated policy, on May 13, 2016, the staff consulted with the State of Tennessee official, regarding the environmental impact of the proposed action. The state official concurred with the EA and finding of no significant impact.

III. Finding of No Significant Impact

The NRC is considering the issuance of an amendment to Facility Operating License No. NFP–90, issued February 7, 1996, and held by TVA for the operation of WBN, Unit 1. The proposed amendment would revise TS 4.2.1, "Fuel Assemblies"; TS 3.5.1 "Accumulators"; SR 3.5.1.4; TS 3.5.4, "Refueling Water Storage Tank"; and SR 3.5.4.3, to increase the maximum number of tritium producing burnable absorber rods and to delete outdated information related to the tritium production program.

As previously discussed, the proposed license amendment would not result in any significant radiological or non-radiological environmental impacts, therefore the NRC has concluded that a FONSI is appropriate. The NRC's EA, included in Section II of this document, is incorporated by reference into this finding.

On the basis of the EA, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has concluded that an environmental impact statement is not necessary for the evaluation of the proposed action.

IV. Availability of Documents

The following table identifies the environmental and other documents cited in this document. These documents are available for public inspection online through ADAMS at *http://www.nrc.gov/reading-rm/adams.html* or in person at the NRC's PDR as previously described.

Document	Date	ADAMS Accession No.
NUREG–0498—Final Environmental Statement Related to Operation of Watts Bar Nuclear Plant, Units 1 and 2.	12/1978	ML082540803
NUREG–0498—Final Environmental Statement Related to the Operation of Watts Bar Nuclear Plant, Units 1 and 2, Supplement 1.	4/1995	ML081430592
Amendment No. 8—Authorized irradiation of 32 lead Test Assembly tritium-producing burnable absorber rods (TPBARs) during Cycle 2.	9/15/1997	ML020780128
Department of Energy NPD–98–181, Tritium Production Core Topical Report	2/8/1999	ML16077A093
Amendment No. 40—Authorized loading up to 2,304 TPBARs	9/23/2002	ML022540925
Environmental Assessment for Amendment No. 40, (67 FR 54926)	8/26/2002	ML022320905
Amendment No. 48—Authorized irradiation of 240 TPBARs during Cycle 6	10/8/2003	ML032880062
Amendment No. 67—Authorized loading of 400 TPBARs during Cycle 9	1/18/2008	ML073520546
Amendment No. 77—Authorized an increase in the maximum number of TPBARs from 400 to 704	5/4/2009	ML090920506
Department of Energy Final Supplemental Environmental Impact Statement for the Production of Tritium in a Commercial Light Water Reactor. DOE/EIS–0288–S1.	2016	(1)
TVA letter to NRC, Application to Revise Technical Specification 4.2.1, "Fuel Assemblies"	3/31/2015	ML15098A446
TVA letter to NRC, Correction to Application to Revise Technical Specification 4.2.1, "Fuel Assemblies"	4/28/2015	ML15124A334
"Watts Bar Nuclear Plant Unit 1, Annual Radioactive Effluent Release Report—2014"	5/1/2015	ML15121A826
NRC letter to TVA, Watts Bar Nuclear Plant, Unit 1—Supplemental Information Needed for Acceptance of Requested Licensing Action Regarding Application to Increase Tritium Producing Absorbing Rods (TAC No. MF6050).	5/14/2015	ML15127A250
TVA letter to NRC, Response to NRC Request to Supplement the Application to Revise Technical Specification 4.2.1, "Fuel Assemblies".	5/27/2015	ML15147A611
TVA letter to NRC, Response to NRC Request to Supplement Application to Revise Technical Specification 4.2.1, "Fuel Assemblies" (WBN–TS–15–03)—Radiological Protection and Radiological Consequences.	6/15/2015	ML15167A359
TVA letter to NRC, Application to Revise Technical Specification 4.2.1, "Fuel Assemblies" (WBN–TS–15–03) (TAC No. MF6050)—Response to NRC Request for Additional Information—Reactor Systems Branch.	9/14/2015	ML15258A204
TVA letter to NRC, Application to Revise Technical Specification 4.2.1, "Fuel Assemblies" (WBN–TS–15–03)—Response to NRC Request for Additional Information—Radiation Protection and Consequence Branch.	9/25/2015	ML15268A568
TVA letter to NRC, Application to Revise Technical Specification 4.2.1, "Fuel Assemblies" (WBN–TS–15–03)(TAC No. MF6050)—Response to NRC Request for Additional Information—Nuclear Performance and Code Review Branch.	11/30/2015	ML15335A468
TVA letter to NRC, Application to Revise Technical Specification 4.2.1, "Fuel Assemblies" (WBN–TS–15–03) (TAC No. MF6050)—Response to NRC Request for Additional Information—Radiation Protection and Consequence Branch.	12/22/2015	ML16054A661
NRC letter to TVA, Audit Report Related to License Amendment Request to Revise Technical Specification 4.2.1, "Fuel Assemblies" (CAC No. MF6050).	12/23/2015	ML15345A424
TVA letter to NRC, Application to Revise Technical Specification 4.2.1, "Fuel Assemblies" (WBN–TS–15–03)—Supplemental Information Related to the Onsite Regulatory Audit at Pacific Northwest National Laboratory.	12/29/2015	ML16004A161
TVA letter to NRC, Application to Revise Technical Specification 4.2.1, "Fuel Assemblies" (WBN–TS–15–03) (TAC No. MF6050)—Supplement to Response to NRC Request for Additional Information—Radiation Protection and Consequence Branch.	2/22/2016	ML16053A513
TVA letter to NRC, Application to Revise Technical Specification 4.2.1, "Fuel Assemblies" (WBN–TS–15–03) (TAC No. MF6050)—Radioactive Waste System Design Basis Source Term Supplement to Response to NRC Request for Additional Information—Radiation Protection and Consequence Branch.	3/31/2016	ML16095A064

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[1] *http://energy.gov/nepa/downloads/eis-0288-s1-epa-notice-availability-final-supplemental-environmental-impact-statement.*

Dated at Rockville, Maryland, this 23rd day of June 2016.

For the Nuclear Regulatory Commission.

Jeanne A. Dion,

Project Manager, Plant Licensing Branch III–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–15867 Filed 7–1–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0001]

Sunshine Act Meeting Notice

DATE: July 4, 11, 18, 25, August 1, 8, 2016.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of July 4, 2016

Thursday, July 7, 2016

9:30 a.m.—Strategic Programmatic Overview of the Reactors Operating Business Line (Public Meeting) (Contact: Trent Wertz: 301–415–1568)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of July 11, 2016—Tentative

There are no meetings scheduled for the week of July 11, 2016.

Week of July 18, 2016—Tentative

Thursday, July 21, 2016

9:30 a.m.—Briefing on Project Aim (Public Meeting) (Contact: Janelle Jessie: 301–415–6775)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of July 25, 2016—Tentative

Thursday, July 28, 2016

9:00 a.m.—Hearing on Combined Licenses for Levy Nuclear Plant, Units 1 and 2: Section 189a. of the Atomic Energy Act Proceeding (Public Meeting) (Contact: Donald Habib: 301–415–1035)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of August 1, 2016—Tentative

There are no meetings scheduled for the week of August 1, 2016.

Week of August 8, 2016—Tentative

There are no meetings scheduled for the week of August 8, 2016.

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: June 29, 2016.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2016–15922 Filed 6–30–16; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0118]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment requests; opportunity to comment, request a hearing, and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of four amendment requests. The amendment requests are for the Cooper Nuclear Station (CNS); Duane Arnold Energy Center (DAEC); and Browns Ferry Nuclear Plant (BFN), Units 1, 2, and 3. For each amendment request, the NRC proposes to determine that it involves no significant hazards consideration. In addition, each amendment request contains sensitive unclassified non-safeguards information (SUNSI).

DATES: Comments must be filed by August 4, 2016. A request for a hearing must be filed by September 6, 2016. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by July 15, 2016.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0118. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lynn Ronewicz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1927, email: *Lynn.Ronewicz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0118 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0118.
- *NRC's Agencywide Documents Access and Management System*

(ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0118, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Pursuant to Section 189a(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies and procedures.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii). If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by September 6, 2016. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by September 6, 2016.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this amendment action, see the application for amendment which is available for public inspection at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

Nebraska Public Power District (NPPD), Docket No. 50–298, Cooper Nuclear Station (CNS), Nemaha County, Nebraska

Date of amendment request: April 21, 2016. A publicly-available version is in ADAMS under Package Accession No. ML16120A367.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The proposed amendment would revise the value of the Safety Limit Minimum Critical Power Ratio (SLMCPR) for two recirculation loop operation (TLO) and for single recirculation loop operation (SLO) in the CNS Technical Specification (TS) 2.1.1.2 based on analysis performed for CNS operation in Cycle 30. Specifically, for TS 2.1.1.2, the amendment will change the value of the Minimum Critical Power Ratio (MCPR) for TLO from greater than to equal to (≥) 1.11 to ≥ 1.12 and the value of the MCPR for SLO from ≥ 1.13 to ≥ 1.14.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The basis of the SLMCPR is to ensure no mechanistic fuel damage is calculated to occur if the limit is not violated. The new SLMCPR values preserve the existing margin to transition boiling. The derivation of the revised SLMCPR for CNS, for incorporation into the Technical Specifications and its use to determine plant and cycle-specific thermal limits, has been performed using Nuclear Regulatory Commission approved methods. The revised SLMCPR values do not change the method of operating the plant and have no effect on the probability of an accident, initiating event or transient.

Based on the above, NPPD concludes that the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes result only from a specific analysis for the CNS core reload design. These changes do not involve any new or different methods for operating the facility. No new initiating events or transients result from these changes.

Based on the above, NPPD concludes that the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

Response: No.

The values of the proposed SLMCPR provide a margin of safety by ensuring that no more than 0.1% of fuel rods are expected to be in a boiling transition if the Minimum Critical Power Ratio limit is not violated. The proposed changes will ensure the appropriate level of fuel protection is maintained. Additionally, operational limits are established based on the proposed SLMCPR to ensure that the SLMCPR is not violated during all modes of operation. This will ensure that the fuel design safety criteria are met (*i.e.,* that at least 99.9% of the fuel rods do not experience transition boiling during normal operation as well as anticipated operational occurrences).

Based on the above, NPPD concludes that the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. John C. McClure, Nebraska Public Power District, Post Office Box 499, Columbus, Nebraska 68602–0499.

NRC Acting Branch Chief: Shaun M. Anderson.

NextEra Energy Duane Arnold, LLC, Docket No. 50–331, Duane Arnold Energy Center (DAEC), Linn County, Iowa

Date of amendment request: March 15, 2016. A publicly-available version is in ADAMS under Package Accession No. ML16077A229.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguard information (SUNSI). The proposed amendment would revise the DAEC Technical Specification (TS) Section 4.3.1, "Fuel Storage, Criticality," and TS Section 4.3.3, "Fuel Storage, Capacity," in accordance with the spent fuel pool criticality safety analysis report enclosed in the application. The amendment would also add a new requirement to TS 5.5, "Programs and Manuals," for a Spent Fuel Pool Neutron Absorber Monitoring Program.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed amendment involves a new spent fuel pool criticality safety analysis and proposes modified or new TS requirements. The new spent fuel pool criticality safety analysis does not involve a physical change to any plant system nor does it involve a change to any of the accident mitigation features previously evaluated.

The proposed amendment does not change or modify the fuel, fuel handling processes, spent fuel storage racks, decay heat generation rate, or the spent fuel pool cooling and cleanup system.

Operation in accordance with the proposed amendment will not significantly increase the probability of a fuel mis-positioning event because the new spent fuel pool criticality safety analysis demonstrates that fuel assemblies that meet the new TS requirements can be stored in any spent fuel pool location without restriction.

There is no dose consequence associated with an abnormal condition since the criticality safety analysis acceptance criteria preclude criticality and does not involve a radiological release.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed amendment involves a new spent fuel pool criticality safety analysis and proposes modified or new TS requirements. The new spent fuel pool criticality safety analysis does not involve a physical change to any plant system.

The proposed amendment does not change or modify the fuel, fuel handling processes, spent fuel storage racks, decay heat generation rate, or the spent fuel pool cooling and cleanup system. The proposed amendment does not change the method of fuel movement or fuel storage and does not create the potential for a new accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

10 CFR 50.68, Criticality Accident Requirements, requires the spent and fresh fuel storage racks to maintain the effective neutron multiplication factor, k_{eff}, less than or equal to 0.95 when fully flooded with unborated water, which includes an allowance for uncertainties. Therefore, for criticality, the required safety margin is 5%, including a conservative margin to account for engineering and manufacturing uncertainties. The new spent fuel pool criticality safety analysis and proposed TS changes continue to satisfy this requirement.

The new spent fuel pool criticality safety analysis does not affect spent fuel heat generation or the spent fuel pool cooling systems. In addition, the radiological consequences of a dropped fuel assembly remain unchanged as the anticipated fuel damage due to a fuel handling accident is unaffected by the implementation of the new spent fuel pool criticality safety analysis. The proposed change reduces the capacity of the spent fuel pool which either does not impact or increases the margin of safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. William Blair, P.O. Box 14000, Juno Beach, Florida 33408–0420.

NRC Branch Chief: David J. Wrona.

NextEra Energy Duane Arnold, LLC, Docket No. 50–331, Duane Arnold Energy Center (DAEC), Linn County, Iowa

Date of amendment request: May 18, 2016. A publicly-available version is in ADAMS under Package Accession No. ML16145A250.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguard information (SUNSI). The proposed amendment would revise the DAEC Technical Specification (TS) Section 2.1.1, "Reactor Core SLs," to change the Safety Limit Minimum Critical Power Ratio (SLMCPR) for two recirculation loop operation and for single recirculation loop operation. The changes would reflect the cycle-specific analysis. The proposed amendment would also remove an outdated historical footnote from TS Table 3.3.5.1–1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below, with NRC staff edits in square brackets:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The SLMCPR ensures that 99.9% of the fuel rods in the core will not be susceptible to boiling transition during normal operation or the most limiting postulated design-basis transient event. The new SLMCPR values preserve the existing margin to the onset of transition boiling; therefore, the probability of fuel damage is not increased as a result of this proposed change.

The determination of the new SLMCPRs has been performed using NRC-approved methods of evaluation. These plant-specific calculations are performed each operating cycle. The new SLMCPR values do not change the method of operating the plant; therefore, they have no effect on the probability of an accident initiating event or transient.

The proposed change does not involve any plant modifications or operational changes that could affect system reliability or performance or that could affect the probability of operator error. The proposed change does not affect any postulated accident precursors, does not affect any accident mitigating systems, and does not introduce any new accident initiation mechanisms.

[The removal of the historical footnote from TS Table 3.3.5.1–1 is administrative in nature and has no impact on accident analysis.]

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The SLMCPR is a TS numerical value, calculated to ensure that during normal operation and during abnormal operational transients, at least 99.9% of all fuel rods in the core do not experience transition boiling if the limit is not violated. The new SLMCPRs are calculated using NRC-approved methodology discussed in NEDE–24011–P–A, "General Electric Standard Application for Reactor Fuel." The proposed change does not involve any new modes of operation, any changes to setpoints, or any plant modifications. The new SLMCPRs have been shown to be acceptable for DAEC Cycle 26 operation. The core operating limits will continue to be developed using NRC-approved methods. The proposed SLMCPRs or methods for establishing the core operating limits do not result in the creation of any new precursors to an accident. The proposed change does not involve any new or different methods for operating the facility. No new initiating events or transients result from the proposed change.

[The removal of the historical footnote from TS Table 3.3.5.1–1 is administrative in nature and has no impact on accident analysis.] Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The new SLMCPRs have been calculated using NRC-approved methods of evaluation with plant and cycle-specific input values for the fuel and core design for the upcoming cycle of operation. The SLMCPR values ensure that 99.9% of the fuel rods in the core will not be susceptible to boiling transition during normal operation or the most limiting postulated design-basis transient event. The MCPR operating limit is set appropriately above the safety limit value to ensure adequate margin when the cycle-specific transients are evaluated. Accordingly, the margin of safety is maintained with the revised values.

[The removal of the historical footnote from TS Table 3.3.5.1–1 is administrative in nature and has no impact on accident analysis.]

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. William Blair, P.O. Box 14000, Juno Beach, Florida 33408–0420.

NRC Branch Chief: David J. Wrona.

Tennessee Valley Authority, Docket Nos. 50–259, 50–260, and 50–296, Browns Ferry Nuclear Plant (BFN), Units 1, 2, and 3, Limestone County, Alabama

Date of amendment request: September 21, 2015, as supplemented by letters dated November 13, December 15, December 15, and December 18, 2015; and February 16, March 8, March 9, March 24, March 28, April 4, April 5, and April 14, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML15282A154 (Package), ML15317A361, ML15351A097, ML15351A113, ML15355A413, ML16049A248, ML16069A142, ML16070A189, ML16085A143, ML16089A054, ML16095A293, ML16096A411, and ML16106A072, respectively.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The proposed amendment would increase the authorized maximum steady-state reactor core power level for each unit from 3,458 megawatt thermal (MWt) to 3,952 MWt. This amendment authorizes an increase of approximately 20 percent above the original licensed thermal power (OLTP) level of 3,293 MWt, and an increase of approximately 14.3 percent above the current licensed thermal power level of 3,458 MWt.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change increases the maximum authorized core power level for BFN from the current licensed thermal power (CLTP) of 3458 MWt to 3952 MWt. Evaluations and analysis of the nuclear steam supply system (NSSS) and balance of plant (BOP) structures, systems, and components (SSCs) that could be affected by the power uprate were performed in accordance with the approaches described in the following.

- GE Nuclear Energy, "Constant Pressure Power Uprate," NEDC–33004P–A (CLTR), Revision 4, dated July 2003
- GE Nuclear Energy, "Generic Guidelines for General Electric Boiling Water Reactor Extended Power Uprate," NEDC–32424P–A (ELTR1), dated February 1999
- GE Nuclear Energy, "Generic Evaluation of General Electric Boiling Water Reactor Extended Power Uprate," NEDC–32523P–A (ELTR2), dated February 1999

The Power Uprate Safety Analysis Report (PUSAR) summarizes the results of safety evaluations performed that justify uprating the licensed thermal power at BFN. The PUSAR uses GEH [General Electric-Hitachi] GE14 fuel as the principal reference fuel type for the evaluation of the impact of EPU [extended power uprate]. However, the BFN units will utilize AREVA ATRIUM 10XM fuel, with some legacy ATRIUM 10 fuel, under EPU conditions. Therefore, the AREVA Fuel Uprate Safety Analysis Report (FUSAR) for Browns Ferry Units 1, 2, and 3 and fuel related reports are provided to supplement the PUSAR and address the impact of EPU conditions on the AREVA fuel in the BFN units. The AREVA analyses contained in the FUSAR have provided disposition of the critical characteristics of the GE14 fuel and have been shown to bound ATRIUM 10XM and ATRIUM 10 fuel.

The fuel-related reports are as follows:

- ANP–3377, Browns Ferry Units 1, 2, and 3 LOCA [Loss-of-Coolant Accident] Break Spectrum Analysis for ATRIUM 10XM Fuel (EPU)
- ANP–3378, Browns Ferry Units 1, 2, and 3 LOCA–ECCS [Emergency Core Cooling System] Analysis MAPLHGR Limits for ATRIUM 10XM Fuel (EPU)
- ANP–3384, Browns Ferry Units 1, 2, and 3 LOCA–ECCS Analysis MAPLHGR Limits for ATRIUM 10 Fuel (EPU)
- ANP–3342, Browns Ferry EPU (120% OLTP) Equilibrium Fuel Cycle Design
- ANP–3372, Browns Ferry Unit 3 Cycle 19 EPU (120% OLTP) LAR [License Amendment Request] Reference Fuel Cycle Design
- ANP–3404, Browns Ferry Unit 3 Cycle 19 Representative Reload Analysis at Extended Power Uprate
- ANP–3343, Nuclear Fuel Design Report Browns Ferry EPU (120% OLTP) Equilibrium Cycle ATRIUM 10XM Fuel
- ANP–3386, Mechanical Design Report for Browns Ferry Units 1, 2 and 3 Extended Power Uprate (EPU) ATRIUM 10XM Fuel Assemblies
- ANP–3385, Mechanical Design Report for Browns Ferry Units 1, 2 and 3 Extended Power Uprate (EPU) ATRIUM 10 Fuel Assemblies
- ANP–3388, Fuel Rod Thermal-Mechanical Evaluation for Browns Ferry Extended Power Uprate
- ANP–3327, Evaluation of AREVA Fuel Thermal-Hydraulic Performance for Browns Ferry at EPU
- FS1–0019629/30, Browns Ferry Unit 3 Cycle 19 MCPR [Minimum Critical Power Ratio] Safety Limit Analysis With SAFLIM3D Methodology
- ANP–2860 Revision 2, Supplement 2, Browns Ferry Unit 1—Summary of Responses to Request for Additional Information, Extension for Use of ATRIUM 10XM Fuel for Extended Power Uprate
- ANP–2637, Boiling Water Reactor Licensing Methodology Compendium
- ANP–3409, Fuel-Related Emergent Regulatory Issues

The evaluations concluded that all plant components, as modified, will continue to be capable of performing their design function at the proposed uprated core power level.

The BFN licensing and design bases, including BFN accident analysis, were also evaluated for the effect of the proposed power increase. The evaluation concluded that the applicable analysis acceptance criteria continue to be met.

Power level is not an initiator of any transient or accident; it is used as an input assumption to equipment design and accident analyses. The proposed change does not affect the release paths or the frequency of release for any accident previously evaluated in the FSAR [Final Safety Analysis Report]. SSCs required to mitigate transients remain capable of performing their design functions considering radiological consequences associated with the effect of the proposed EPU. The source terms used to evaluate the radiological consequences were reviewed and were determined to bound operation at EPU power levels. The results of EPU accident evaluations do not exceed NRC-approved acceptance limits.

The spectrum of postulated accidents and transients were reviewed and were shown to meet the regulatory criteria to which BFN is currently licensed. In the area of fuel and core design, the Safety Limit Minimum Critical Power Ratio (SLMCPR) and other Specified Acceptable Fuel Design Limits (SAFDLs) are still met. Continued compliance with the SLMPCR and other SAFDLs is confirmed on a cycle specific basis consistent with the criteria accepted by the NRC.

Challenges to the reactor coolant pressure boundary were evaluated at the EPU conditions of pressure, temperature, flow, and radiation and found to meet the acceptance criteria for allowable stresses. Adequate overpressure margin is maintained.

Challenges to the containment were also evaluated. The containment and its associated cooling system continue to meet applicable regulatory requirements. The calculated post event suppression pool temperatures remain within design limits, while ensuring adequate net positive suction head is maintained for required emergency core cooling system pumps.

Radiological releases were evaluated and found to be within the regulatory limits of 10 CFR 50.67, Accident Source Terms.

The modifications and methodology associated with the elimination of containment accident pressure credit do not change the design functions of the systems. By maintaining these functions, they do not significantly increase the probability or consequences of an accident previously evaluated.

The non-safety-related Replacement Steam Dryer (RSD) must function to maintain structural integrity and avoid generation of loose parts that may affect other SSCs. The RSD analyses demonstrate the structural integrity of the steam dryer is maintained at EPU conditions. Therefore, the RSD does not significantly increase the probability or consequences of an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change increases the maximum authorized core power level for BFN from the current licensed thermal power (CLTP) of 3458 MWt to 3952 MWt. An evaluation of the equipment that could be affected by the power uprate has been performed. No new accident scenarios or equipment failure modes were identified. The full spectrum of accident considerations was evaluated and no new or different kinds of accidents were identified. For BFN, the standard evaluation methods outlined in the CLTR, ELTR1, ELTR2, PUSAR, FUSAR, and fuel related reports were applied to the capability of existing or modified safety-related plant equipment. No new accidents or event precursors were identified.

All SSCs previously required for mitigation of a transient remain capable of fulfilling their intended design functions. The proposed increase in power does not adversely affect safety-related systems or components and does not challenge the performance or integrity of any safety-related systems. The change does not adversely affect any current system interfaces or create any new interfaces that could result in an accident or malfunction of a different kind than was previously evaluated. Operating at the proposed EPU power level does not create any new accident initiators or precursors.

The modifications and methodology associated with the elimination of containment accident pressure credit do not change the design functions of the systems. The systems are not accident initiators and by maintaining their current function they do not create the possibility of a new or different kind of accident.

The new RSD does not have any new design functions. RSD analyses demonstrate that the RSD will be capable of performing the design function of maintaining structural integrity. Therefore, there are no new or different kinds of accidents from those previously evaluated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Based on the analyses of the proposed power increase, the relevant design and safety acceptance criteria will be met without significant adverse effects or reduction in margins of safety. The analyses supporting EPU have demonstrated that the BFN SSCs are capable of safely performing at EPU conditions. The analyses identified and defined the major input parameters to the NSSS, and NSSS design transients, and evaluated the capability of the primary containment, NSSS fluid systems, NSSS and BOP components, as appropriate. Radiological consequences of design basis events remain within regulatory limits and are not increased significantly. The analyses confirmed that NSSS and BOP SSCs are capable of achieving EPU conditions without significant reduction in margins of safety, with the modifications discussed in this application.

Analyses have shown that the integrity of primary fission product barriers will not be significantly affected as a result of the power increase. Calculated loads on SSCs important to safety have been shown to remain within design allowables under EPU conditions for all design basis event categories. Plant response to transients and accidents do not result in exceeding acceptance criteria.

As appropriate, the evaluations that demonstrate acceptability of EPU have been performed using methods that have either been reviewed and approved by the NRC staff, or that are in compliance with regulatory review guidance and standards established for maintaining adequate margins of safety. These evaluations demonstrate that there are no significant reductions in the margins of safety.

Maximum power level is one of the inherent inputs that determine the safe operating range defined by the accident analyses. The Technical Specifications ensure that BFN is operated within the bounds of the inputs and assumptions used in the accident analyses. The acceptance criteria for the accident analyses are conservative with respect to the operating conditions defined by the Technical Specifications. The engineering reviews performed for the constant pressure EPU confirm that the accident analyses criteria are met at the revised maximum allowed thermal power of 3952 MWt. Therefore, the adequacy of the renewed Facility Operating License and Technical Specifications to maintain the plant in a safe operating range is also confirmed, and the increase in maximum allowable power level does not involve a significant decrease in a margin of safety.

The modifications and methodology associated with the elimination of containment accident pressure credit do not change the design functions within the applicable limits. The credit is associated with accident or event response and does not significantly affect accident initiators by maintaining their current functions and does not create the possibility of a new or different kind of accident. The proposed Technical Specifications associated with these modifications ensure that BFN is operated within the bounds of the inputs and assumptions used in the accident analyses.

The steam dryer is being replaced in order to ensure adequate margin to the established structural requirements is maintained. The new RSD does not have any new design functions and an analysis was performed to confirm it will be capable of maintaining its structural integrity. The power ascension test plan will verify that the RSD conservatively meets the vibration and stress requirements.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Dr., WT 6A–K, Knoxville, Tennessee 37902.

NRC Branch Chief: Benjamin G. Beasley.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Nebraska Public Power District, Docket No. 50–298, Cooper Nuclear Station, Nemaha County, Nebraska

NextEra Energy Duane Arnold, LLC, Docket No. 50–331, Duane Arnold Energy Center, Linn County, Iowa

Tennessee Valley Authority, Docket Nos. 50–259, 50–260, and 50–296, Browns Ferry Nuclear Plant, Units 1, 2, and 3, Limestone County, Alabama

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

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[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 17th day of June 2016.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/Activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no "need" or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.

[FR Doc. 2016–14999 Filed 7–1–16; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–159 and CP2016–230; MC2016–160 and CP2016–231; MC2016–161 and CP2016–232]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 6, 2016 (Comment due date applies to all Docket Nos. listed above)

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service has filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The requests(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2016–159 and CP2016–230; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Contract 229 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* June 27, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Kenneth R. Moeller; *Comments Due:* July 6, 2016.

2. *Docket No(s).:* MC2016–160 and CP2016–231; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 10 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* June 27, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Jennaca D. Upperman; *Comments Due:* July 6, 2016.

3. *Docket No(s).:* MC2016–161 and CP2016–232; *Filing Title:* Request of the United States Postal Service to Add Priority Mail Express Contract 38 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data; *Filing Acceptance Date:* June 27, 2016; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Natalie R. Ward; *Comments Due:* July 6, 2016.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–15740 Filed 7–1–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on June 27, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 229 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–159, CP2016–230.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–15771 Filed 7–1–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on June 27, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express Contract 38 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–161, CP2016–232.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–15773 Filed 7–1–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* July 5, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on June 27, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 10 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–160, CP2016–231.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–15772 Filed 7–1–16; 8:45 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. *Title and purpose of information collection:* Medical Reports; OMB 3220–0038. Under sections 2(a)(1)(iv) and 2(a)(1)(v) of the Railroad Retirement Act (RRA), annuities are payable to qualified railroad employees whose physical or mental condition makes them unable to (1) work in their regular occupation (occupational disability) or (2) work at all (total disability). The requirements

for establishing disability and proof of continuing disability under the RRA are prescribed in 20 CFR 220.

Annuities are also payable to (1) qualified spouses and widow(ers) under sections 2(c)(1)(ii)(C) and 2(d)(1)(ii) of the RRA who have a qualifying child who became disabled before age 22; (2) surviving children on the basis of disability under section 2(d)(1)(iii)(C), if the child's disability began before age 22; and (3) widow(er)s on the basis of disability under section 2(d)(1)(i)(B). To meet the disability standard, the RRA provides that individuals must have a permanent physical or mental condition that makes them unable to engage in any regular employment.

Under section 2(d)(1)(v) of the RRA, annuities are also payable to remarried widow(er)s and surviving divorced spouses on the basis of, among other things, disability or having a qualifying disabled child in care. However, the disability standard in these cases is that found in the Social Security Act. That is, individuals must be unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment. The RRB also determines entitlement to a Period of Disability and entitlement to early Medicare based on disability for qualified claimants in accordance with Section 216 of the Social Security Act.

When making disability determinations, the RRB needs evidence from acceptable medical sources. The RRB currently utilizes Forms G–3EMP, Report of Medical Condition by Employer; G–197, Authorization to Disclose Information to the Railroad Retirement Board; G–250, Medical Assessment; G–250A, Medical Assessment of Residual Functional Capacity; G–260, Report of Seizure Disorder; RL–11B, Disclosure of Hospital Medical Records; RL–11D, Disclosure of Medical Records from a State Agency; and RL–250, Request for Medical Assessment, to obtain the necessary medical evidence. The RRB proposes no revisions to these forms.

In support of the RRB's Disability Program Improvement Project to enhance/improve disability case processing and overall program integrity, the RRB proposes the addition of proposed Form RL–11D1, Request for Medical Evidence from Employers, to the information collection. Form RL–11D1 will be mailed by an RRB field office to railroad and nonrailroad employers to obtain any medical evidence regarding the employee's disability that they may have acquired within the last 18 months. A copy of the employee signed Form G–197 will be enclosed with the RL–11D1. The employer will return the RL–11D1 to RRB Headquarters certifying that they either have submitted the requested medical evidence or that they have no medical evidence to submit. One response is requested of each respondent. Completion is voluntary.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–3EMP	600	10	100
G–197	6,000	10	1,000
G–250	11,950	30	5,975
G–250A	50	20	17
G–260	100	25	42
RL–11B	5,000	10	833
RL–11D	250	10	42
RL–11D1	600	20	200
RL–250	11,950	10	1,992
Total	36,500	....	10,201

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.* Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to *Charles.Mierzwa@RRB.GOV.* Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2016–15887 Filed 7–1–16; 8:45 am]

BILLING CODE 7905–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Public Comment on an Annotated Outline for the Fourth National Climate Assessment

ACTION: Notice of request for public comment.

SUMMARY: With this notice, The U.S. Global Change Research Program (USGCRP) seeks public comment on the proposed content and scope of the Fourth National Climate Assessment (NCA4) as indicated by the draft outline presented here. A Request for Information in 2015 sought public input on the sustained National Climate Assessment (NCA) process more generally (80 FR 26105, *https://federalregister.gov/a/2015-10352*). The outline for NCA4 is informed by that previously received public input.

General topics on which public comment is requested, in addition to the proposed outline, include: (1) Ways to make the assessment information accessible and useful to multiple audiences; (2) the specific types of detailed information at regional scales that would be most useful; (3) suggestions for how to best describe risks and impacts, as well as potential opportunities to reduce those risks and impacts on sectors of the economy as well as natural and social systems; (4) suggestions for new approaches to topics addressed in previous assessments; and (5) suggestions regarding overarching themes that NCA4 should consider addressing.

A call for author nominations and technical inputs may soon be posted in one or more subsequent **Federal Register** Notices. A draft of NCA4 will also be released for public comment prior to its final release. Background information, additional details, and instructions for submitting comments can be found at *www.globalchange.gov/*

notices. For more information about the NCA and access to previous NCA reports and activities, please see *http://assessment.globalchange.gov.* Responses to the questions below can be entered via the Web site noted above.

DATES: Comments will be accepted through July 29, 2016.

ADDRESSES: Comments from the public will be accepted electronically via *http://www.globalchange.gov/notices.* Instructions for submitting comments are on the Web site. Submitters may enter text or upload files in response to this notice.

Instructions: Response to this Request for Comment is voluntary. Respondents need not reply to all questions or topics; however, they should clearly indicate the question or topic to which they are responding. Responses may be used by the U.S. Government for program planning on a non-attribution basis. OSTP therefore requests that no business proprietary information or copyrighted information be submitted in response to this Request for Comment. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: Emily Therese Cloyd, (202) 223–6262, *ecloyd@usgcrp.gov,* U.S. Global Change Research Program.

SUPPLEMENTARY INFORMATION: USGCRP is mandated under the Global Change Research Act (GCRA) of 1990 to conduct a quadrennial NCA. Under its current decadal strategic plan (*http://go.usa.gov/3qGU4*), USGCRP is building sustained assessment capacity to support the Nation's ability to understand, anticipate, and respond to risks and potential impacts brought about by global environmental change, namely the human-caused buildup of greenhouse gases in our atmosphere that is causing climate change. The last NCA from 2014 (NCA3: *http://nca2014.globalchange.gov*) and the process to develop it provide a foundation for subsequent activities and reports.

Recent special assessments by the U.S. Government will be utilized for NCA4, including: The Impacts of Climate Change on Human Health in the United States (*https://health2016.globalchange.gov/*); Climate Change, Global Food Security, and the U.S. Food System (*http://www.usda.gov/oce/climate_change/FoodSecurity.htm*); and Effects of Drought on Forests and Rangelands in the United States (*http://www.fs.fed.us/science-technology/climate-change/drought-forests-and-rangelands*). Other USGCRP special reports under development include the Second State of the Carbon Cycle Report (SOCCR–2, *https://www.carboncyclescience.us/news/federal-register-notice-2nd-state-carbon-cycle-report-soccr-2*) and the Climate Science Special Report (CSSR, *https://www.federalregister.gov/articles/2016/03/31/2016-07208/united-states-global-change-research-program*).

There will be a number of overarching themes and perspectives in NCA4 that are, in part, responsive to needs and gaps identified in NCA3. The following are likely to be such themes throughout NCA4:

○ NCA4 will attempt to highlight advancements or improvements, since NCA3, in understanding of the science of human-induced climate change and the resulting implications for the United States.

○ For risks and potential impacts, NCA4 will identify populations of concern, which was a theme highlighted in The Impacts of Climate Change on Human Health in the United States (2016).

○ Major research needs, key uncertainties, and information gaps will be identified.

○ Current and future risks associated with climate change will be characterized with quantifiable metrics wherever possible, and with the needs of multiple audiences in mind.

○ Consistent treatment of different timeframes of interest will be sought throughout NCA4, with emphasis on the near-term (*i.e.,* over the next few decades) trends and projections to inform adaptation needs, the long-term (*i.e.,* latter half of this century) projections that are more scenario dependent, and in some cases timeframes well past 2100 to indicate legacy effects of the human influence on the climate and oceans.

Comments are sought on these proposed overarching themes. Additional suggestions will be reviewed as they relate to the proposed structure of the report.

What follows is a proposed high-level and draft annotated outline intended to guide the scope and content for NCA4. Public comments are sought on all aspects of this draft outline. The proposed outline is presented here in five parts: (1) Introduction and context for NCA4; (2) the foundational physical science; (3) human health and welfare, societal and environmental areas that are vulnerable to a changing climate; (4) regional analyses within the United States; and (5) identifying the information needed to support climate change adaptation, increased resiliency, and risk reduction.

1. Introduction and Context for NCA4

The introductory and context-setting sections of the NCA4 will describe:

○ Context for the NCA4 as noted above, including the NCA's relation to complementary domestic and international assessment efforts.

○ Advancements in science since NCA3 (2014), as well as any new approaches or differences in scope relative to NCA3. This information will include the special assessments completed or in-progress post-NCA3, in particular those under the auspices of USGCRP (some examples of these special assessments are provided throughout this notice).

○ Changing global and national conditions that influence (1) drivers of climate change, namely the activities that lead to emissions and thus the atmospheric buildup of greenhouse gas concentrations; and (2) resiliency and vulnerabilities, such as demographic change and economic development.

○ The geographic scope (see section 5) and the temporal scope (*e.g.,* recent historic to next 25 to 100 years) of NCA4. The lexicon used for the confidence and uncertainty levels associated with key statements and findings (and accompanying traceable accounts) may be similar to that used in the recent climate change and human health assessment (*https://health2016.globalchange.gov/documenting-uncertainty*).

2. The Foundational Physical Science (Based on the Climate Science Special Report)

The USGCRP is in the process of developing the Climate Science Special Report (CSSR). The CSSR will highlight advances in the physical science of climate change since NCA3 (2014), and will provide the primary scientific underpinnings and framing for the entire NCA4. The **Federal Register** Notice for the CSSR can be found at *https://www.federalregister.gov/articles/2016/03/31/2016-07208/united-states-global-change-research-program.* To briefly summarize here, it will generally cover:

○ Observations of changes in: Atmospheric composition, radiative forcing, temperature, precipitation, large-scale climate modes (*e.g.,* El Nino events), drought, floods and associated hydrologic events (streamflow, snowpack), sea level rise, ice sheet dynamics, biogeochemistry of land and marine systems, climate variability, ocean acidification, extreme storms such as hurricanes, atmospheric rivers, polar changes including permafrost and land-ice dynamics, and attribution of physical and biophysical processes to human activities.

○ Future projections of changes in the aforementioned climate system processes will be based on modeling results of the Coupled Modeled Intercomparison Project Phase 5 (CMIP5) driven by the emissions scenarios and Representative Concentration Pathways (RCPs) as used in the IPCC Fifth Assessment Report (*e.g., http://sedac.ipcc-data.org/ddc/ar5_scenario_process/RCPs.html*). Future projections will include perspectives on mitigation pathways.

3. Human Health and Welfare, Societal and Environmental Vulnerabilities to a Changing Climate

This section of NCA4 will provide national-level overviews of observed and projected future trends and potential effects in key areas of concern for people and the environment, including human health, social well being, and natural systems. These same areas will be addressed to varying degrees in each of the regional sections of the outline described under Part 4.

Within each of these areas, non-climatic trends (*e.g.,* population changes) will be briefly discussed in order to set a broader context within which climate change effects can be understood. Observed and projected risks, impacts and potential benefits as a result of climate change will be identified in each of these areas, with quantifiable metrics wherever possible. The role of extreme events in each area will be addressed where possible. In addition, potential adaptive measures to minimize risks will be described for each area, to the extent these are identified in the published literature.

The GCRA of 1990 requires that the NCA analyze "the effects of global change on the natural environment, agriculture, energy production and use, land and water resources, transportation, human health and welfare, human social systems, and biological diversity."

In addition to these mandated topics, the following additional specific areas are proposed for inclusion in NCA4: Effects on tribal and indigenous communities; coastal effects; ocean acidification and marine resources; and key international effects, particularly those that may raise environmental, humanitarian, trade, or security issues for the United States. Cross-sectoral issues where interactions can result in significant effects are also being proposed in this section of NCA4; these potentially include (but are not limited to): The water-energy-land nexus; the interactions among biodiversity, land use, and climate; and linkages between air quality and climate.

4. Regional Analyses Within the United States

Under this proposed outline, the regional detail for each of the areas described in Part 3 above will be placed in this section of the report. In other words, Part 3 will provide more generalized information at a national level, whereas Part 4 will go into greater depth to provide information at sub-national and regional levels.

NCA3 included the following regions of the United States (see *http://nca2014.globalchange.gov/report#section-1948*): Northeast, Southeast and the Caribbean, Midwest, Great Plains, Southwest, Northwest, Alaska, Hawaii and Pacific Islands, Oceans and Coasts. The proposed regional breakout for NCA4 is the same with the exception of the Great Plains; because that was such a large region, stretching from the Gulf Coast to the Canadian border, it will be divided into two regions: Northern and Southern Plains.

In addition to the themes for each area described in Part 3, the regional sections in Part 4 will also include State-level information as appropriate and where available, as well as urban and rural case studies where possible to showcase, with local specificity, climate trends, potential risks, and resiliency planning.

5. Identifying the Information Needed To Support Climate Change Adaptation, Increased Resiliency, and Risk Reduction

This part of NCA4 will focus on identifying near-term needs and opportunities for adaptive measures and resiliency planning in the face of observed and projected changes in climate, as well as the dependency of risk and potential impacts on greenhouse gas emissions scenarios over the longer term. NCA4 is not a policy document, and as such will not be evaluating policy measures, actions, instruments or mechanisms to deliver or incentivize either adaptation or mitigation responses at any level of government. Rather, the intention of this part of NCA4 is to inform the Nation, and different regions within the Nation, about near-term adaptation needs over the next few decades that are likely to persist regardless of emissions pathway, and, over the longer term, the reduced and/or avoided levels of risks and impacts in the United States, as a result of different levels of global greenhouse gas mitigation.

Adaptation needs and opportunities will be drawn from relevant information from Parts 2, 3 and 4 as outlined above.

In addition to physical metrics of changing risks and potential impacts over time under different greenhouse gas emissions scenarios, analysis of costs of adaptation options and potential impacts (or avoided impacts) will be included where possible, in part with input from recent EPA efforts, such as the report on Climate Change in the United States: Benefits of Global Action (*https://www.epa.gov/cira*).

Case studies and links to decision-support tools (*e.g.,* the Climate Resilience Toolkit, *http://toolkit.climate.gov*) will also be included here.

Public comments are sought on all of the draft outline sections described above for NCA4.

Stacy L. Murphy,

Operations Manager/Acting Security Officer.

[FR Doc. 2016–15807 Filed 7–1–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78179; File No. 4–700]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17–2; Notice of Filing of Proposed Plan for the Allocation of Regulatory Responsibilities Between the Financial Industry Regulatory Authority, Inc. and the Investors' Exchange LLC

June 28, 2016.

Pursuant to Section 17(d) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 17d–2 thereunder,[2] notice is hereby given that on June 20, 2016, the Financial Industry Regulatory Authority, Inc. ("FINRA") and the Investors' Exchange LLC ("IEX") (together with FINRA, the "Parties") filed with the Securities and Exchange Commission ("Commission" or "SEC") a plan for the allocation of regulatory responsibilities, dated June 20, 2016 ("17–2 Plan" or the "Plan"). The Commission is publishing this notice to solicit comments on the 17–2 Plan from interested persons.

I. Introduction

Section 19(g)(1) of the Act,[3] among other things, requires every self-regulatory organization ("SRO") registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) or Section 19(g)(2) of the Act.[4] Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO ("common members"). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

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[1] 15 U.S.C. 78q(d).

[2] 17 CFR 240.17–2.

[3] 15 U.S.C. 78s(g)(1).

Section 17(d)(1) of the Act[5] was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.[6] With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17–2 under the Act.[7] Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority ("DEA") to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.[8] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO's obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17–2 under the Act.[9] Rule 17–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17–2, the Commission may declare such a plan effective if, after providing for appropriate notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors; to foster cooperation and coordination among the SROs; to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system; and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. Proposed Plan

The proposed 17–2 Plan is intended to reduce regulatory duplication for firms that are common members of both IEX and FINRA.[10] Pursuant to the proposed 17–2 Plan, FINRA would assume certain examination and enforcement responsibilities for common members with respect to certain applicable laws, rules, and regulations.

The text of the Plan delineates the proposed regulatory responsibilities with respect to the Parties. Included in the proposed Plan is an exhibit (the "IEX Certification of Common Rules," referred to herein as the "Certification") that lists every IEX rule, and select federal securities laws, rules, and regulations, for which FINRA would bear responsibility under the Plan for overseeing and enforcing with respect to IEX members that are also members of FINRA and the associated persons therewith ("Dual Members").

Specifically, under the 17d–2 Plan, FINRA would assume examination and enforcement responsibility relating to compliance by Dual Members with the rules of IEX that are substantially similar to the applicable rules of FINRA,[11] as well as any provisions of the federal securities laws and the rules and regulations thereunder delineated in the Certification ("Common Rules"). In the event that a Dual Member is the subject of an investigation relating to a transaction on IEX, the plan acknowledges that IEX may, in its discretion, exercise concurrent jurisdiction and responsibility for such matter.[12]

Under the Plan, IEX would retain full responsibility for surveillance and enforcement with respect to trading activities or practices involving IEX's own marketplace, including, without limitation, registration pursuant to its applicable rules of associated persons (*i.e.,* registration rules that are not Common Rules); its duties as a DEA pursuant to Rule 17d–1 under the Act; and any IEX rules that are not Common Rules.[13]

The text of the proposed 17d–2 Plan is as follows:

AGREEMENT BETWEEN FINANCIAL INDUSTRY REGULATORY AUTHORITY, INC. AND INVESTORS' EXCHANGE LLC PURSUANT TO RULE 17d–2 UNDER THE SECURITIES EXCHANGE ACT OF 1934

This Agreement, by and between the Financial Industry Regulatory Authority, Inc. ("FINRA") and Investors' Exchange LLC ("IEX"), is made this 20th day of June, 2016 (the "Agreement"), pursuant to Section 17(d) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 17d–2 thereunder, which permits agreements between self-regulatory organizations to allocate regulatory responsibility to eliminate regulatory duplication. FINRA and IEX may be referred to individually as a "party" and together as the "parties."

WHEREAS, FINRA and IEX desire to reduce duplication in the examination and surveillance of their Dual Members (as defined herein) and in the filing and processing of certain registration and membership records; and

WHEREAS, FINRA and IEX desire to execute an agreement covering such subjects pursuant to the provisions of Rule 17d–2 under the Exchange Act and to file such agreement with the Securities and Exchange Commission (the "SEC" or "Commission") for its approval.

NOW, THEREFORE, in consideration of the mutual covenants contained hereinafter, FINRA and IEX hereby agree as follows:

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[4] 15 U.S.C. 78q(d) and 15 U.S.C. 78s(g)(2), respectively.

[5] 15 U.S.C. 78q(d)(1).

[6] *See* Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

[7] 17 CFR 240.17d–1 and 17 CFR 240.17–2, respectively.

[8] *See* Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

[9] *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

[10] The proposed 17–2 Plan refers to these common members as "Dual Members." *See* Paragraph 1(c) of the proposed 17–2 Plan.

[11] *See* paragraph 1(b) of the proposed 17d–2 Plan (defining Common Rules). *See also* paragraph 1(f) of the proposed 17d–2 Plan (defining Regulatory Responsibilities). Paragraph 2 of the Plan provides that annually, or more frequently as required by changes in either IEX rules or FINRA rules, the parties shall review and update, if necessary, the list of Common Rules. Further, paragraph 3 of the Plan provides that IEX shall furnish FINRA with a list of Dual Members, and shall update the list no less frequently than once each calendar quarter.

[12] *See* paragraph 6 of the proposed 17d–2 Plan.

[13] *See* paragraph 2 of the proposed 17d–2 Plan.

1. **Definitions.** Unless otherwise defined in this Agreement or the context otherwise requires, the terms used in this Agreement shall have the same meaning as they have under the Exchange Act and the rules and regulations thereunder. As used in this Agreement, the following terms shall have the following meanings:

(a) "*IEX Rules*" or "*FINRA Rules*" shall mean: (i) the rules of IEX, or (ii) the rules of FINRA, respectively, as the rules of an exchange or association are defined in Exchange Act Section 3(a)(27).

(b) "*Common Rules*" shall mean IEX Rules that are substantially similar to the applicable FINRA Rules and certain provisions of the Exchange Act and SEC rules set forth on *Exhibit 1* in that examination or surveillance for compliance with such provisions and rules would not require FINRA to develop one or more new examination or surveillance standards, modules, procedures, or criteria in order to analyze the application of the provision or rule, or a Dual Member's activity, conduct, or output in relation to such provision or rule; provided, however, Common Rules shall not include the application of the SEC, IEX or FINRA rules as they pertain to violations of insider trading activities, which is covered by a separate 17d–2 Agreement by and among BATS Exchange, Inc., BATS Y-Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the NASDAQ Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange LLC, NYSE Amex LLC, and NYSE Arca Inc., effective December 16, 2011, as may be amended from time to time.

(c) "*Dual Members*" shall mean those IEX members that are also members of FINRA and the associated persons therewith.

(d) "*Effective Date*" shall be the date this Agreement is approved by the Commission.

(e) "*Enforcement Responsibilities*" shall mean the conduct of appropriate proceedings, in accordance with FINRA's Code of Procedure (the Rule 9000 Series) and other applicable FINRA procedural rules, to determine whether violations of Common Rules have occurred, and if such violations are deemed to have occurred, the imposition of appropriate sanctions as specified under FINRA's Code of Procedure and sanctions guidelines.

(f) "*Regulatory Responsibilities*" shall mean the examination responsibilities, surveillance responsibilities and Enforcement Responsibilities relating to compliance by the Dual Members with the Common Rules and the provisions of the Exchange Act and the rules and regulations thereunder, and other applicable laws, rules and regulations, each as set forth on *Exhibit 1* attached hereto.

2. **Regulatory and Enforcement Responsibilities.** FINRA shall assume Regulatory Responsibilities and Enforcement Responsibilities for Dual Members. Attached as *Exhibit 1* to this Agreement and made part hereof, IEX furnished FINRA with a current list of Common Rules and certified to FINRA that such rules that are IEX Rules are substantially similar to the corresponding FINRA Rules (the "Certification"). FINRA hereby agrees that the rules listed in the Certification are Common Rules as defined in this Agreement. Each year following the Effective Date of this Agreement, or more frequently if required by changes in either the rules of IEX or FINRA, IEX shall submit an updated list of Common Rules to FINRA for review which shall add IEX Rules not included in the current list of Common Rules that qualify as Common Rules as defined in this Agreement; delete IEX Rules included in the current list of Common Rules that no longer qualify as Common Rules as defined in this Agreement; and confirm that the remaining rules on the current list of Common Rules continue to be IEX Rules that qualify as Common Rules as defined in this Agreement. Within 30 days of receipt of such updated list, FINRA shall confirm in writing whether the rules listed in any updated list are Common Rules as defined in this Agreement. Notwithstanding anything herein to the contrary, it is explicitly understood that the term "Regulatory Responsibilities" does not include, and IEX shall retain full responsibility for (unless otherwise addressed by separate agreement or rule) (collectively, the "Retained Responsibilities") the following:

(a) surveillance, examination, investigation and enforcement with respect to trading activities or practices involving IEX's own marketplace for rules that are not Common Rules;

(b) registration pursuant to its applicable rules of associated persons (*i.e.,* registration rules that are not Common Rules);

(c) discharge of its duties and obligations as a Designated Examining Authority pursuant to Rule 17d-1 under the Exchange Act; and

(d) any IEX Rules that are not Common Rules, except for IEX Rules for IEX Services LLC as provided in paragraph 6.

3. **Dual Members.** Prior to the Effective Date, IEX shall furnish FINRA with a current list of Dual Members, which shall be updated no less frequently than once each quarter.

4. **No Charge.** There shall be no charge to IEX by FINRA for performing the Regulatory Responsibilities and Enforcement Responsibilities under this Agreement except as otherwise agreed by the parties, either herein or in a separate agreement.

5. **Applicability of Certain Laws, Rules, Regulations or Orders.** Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the Commission. To the extent such statute, rule or order is inconsistent with this Agreement, the statute, rule or order shall supersede the provision(s) hereof to the extent necessary for them to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

6. **Notification of Violations.**

(a) In the event that FINRA becomes aware of apparent violations of any IEX Rules, which are not listed as Common Rules, discovered pursuant to the performance of the Regulatory Responsibilities assumed hereunder, FINRA shall notify IEX of those apparent violations for such response as IEX deems appropriate.

(b) In the event that IEX becomes aware of apparent violations of any Common Rules, discovered pursuant to the performance of the Retained Responsibilities, IEX shall notify FINRA of those apparent violations and such matters shall be handled by FINRA as provided in this Agreement. With respect to apparent violations of IEX Services LLC FINRA shall not make referrals to IEX pursuant to this paragraph 6. Such apparent violations shall be processed by, and enforcement proceedings in respect thereto will be conducted by, FINRA as provided in this Agreement.

(c) Apparent violations of Common Rules shall be processed by, and enforcement proceedings in respect thereto shall be conducted by FINRA as provided hereinbefore; provided, however, that in the event a Dual Member is the subject of an investigation relating to a transaction on IEX, IEX may in its discretion assume concurrent jurisdiction and responsibility.

(d) Each party agrees to make available promptly all files, records and witnesses necessary to assist the other in its investigation or proceedings.

7. **Continued Assistance.**

(a) FINRA shall make available to IEX all information obtained by FINRA in the performance by it of the Regulatory Responsibilities hereunder with respect to the Dual Members subject to this Agreement. In particular, and not in limitation of the foregoing, FINRA shall furnish IEX any information it obtains about Dual Members which reflects adversely on their financial condition. IEX shall make available to FINRA any information coming to its attention that reflects adversely on the financial condition of Dual Members or indicates possible violations of applicable laws, rules or regulations by such firms.

(b) The parties agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations. Neither party shall assert regulatory or other privileges as against the other with respect to documents or information that is required to be shared pursuant to this Agreement.

(c) The sharing of documents or information between the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

8. **Statutory Disqualifications.** When FINRA becomes aware of a statutory disqualification as defined in the Exchange Act with respect to a Dual Member, FINRA shall determine pursuant to Sections 15A(g) and/or Section 6(c) of the Exchange Act the acceptability or continued applicability of the person to whom such disqualification applies and keep IEX advised of its actions in this regard for such subsequent proceedings as IEX may initiate.

9. **Customer Complaints.** IEX shall forward to FINRA copies of all customer complaints involving Dual Members received by IEX relating to FINRA's Regulatory Responsibilities under this Agreement. It shall be FINRA's responsibility to review and take appropriate action in respect to such complaints.

10. **Advertising.** FINRA shall assume responsibility to review the advertising of Dual Members subject to the Agreement, provided that such material is filed with FINRA in accordance with FINRA's filing procedures and is accompanied with any applicable filing fees set forth in FINRA Rules.

11. **No Restrictions on Regulatory Action.** Nothing contained in this Agreement shall restrict or in any way encumber the right of either party to conduct its own independent or concurrent investigation, examination or enforcement proceeding of or against Dual Members, as either party, in its sole discretion, shall deem appropriate or necessary.

12. **Termination.** This Agreement may be terminated by IEX or FINRA at any time upon the approval of the Commission after one (1) year's written notice to the other party.

13. **Arbitration.** In the event of a dispute between the parties as to the operation of this Agreement, IEX and FINRA hereby agree that any such dispute shall be settled by arbitration in Washington, DC in accordance with the rules of the American Arbitration Association then in effect, or such other procedures as the parties may mutually agree upon. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction. Each party acknowledges that the timely and complete performance of its obligations pursuant to this Agreement is critical to the business and operations of the other party. In the event of a dispute between the parties, the parties shall continue to perform their respective obligations under this Agreement in good faith during the resolution of such dispute unless and until this Agreement is terminated in accordance with its provisions. Nothing in this Section 13 shall interfere with a party's right to terminate this Agreement as set forth herein.

14. **Notification of Members.** IEX and FINRA shall notify Dual Members of this Agreement after the Effective Date by means of a uniform joint notice.

15. **Amendment.** This Agreement may be amended in writing duly approved by each party. All such amendments must be filed with and approved by the Commission before they become effective.

16. **Limitation of Liability.** Neither FINRA nor IEX nor any of their respective directors, governors, officers or employees shall be liable to the other party to this Agreement for any liability, loss or damage resulting from or claimed to have resulted from any delays, inaccuracies, errors or omissions with respect to the provision of Regulatory Responsibilities as provided hereby or for the failure to provide any such responsibility, except with respect to such liability, loss or damages as shall have been suffered by one or the other of FINRA or IEX and caused by the willful misconduct of the other party or their respective directors, governors, officers or employees. No warranties, express or implied, are made by FINRA or IEX with respect to any of the responsibilities to be performed by each of them hereunder.

17. **Relief from Responsibility.** Pursuant to Sections 17(d)(1)(A) and 19(g) of the Exchange Act and Rule 17d–2 thereunder, FINRA and IEX join in requesting the Commission, upon its approval of this Agreement or any part thereof, to relieve IEX of any and all responsibilities with respect to matters allocated to FINRA pursuant to this Agreement; provided, however, that this Agreement shall not be effective until the Effective Date.

18. **Severability.** Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

19. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and such counterparts together shall constitute one and the same instrument.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, each party has executed or caused this Agreement to be executed on its behalf by a duly authorized officer as of the date first written above.

INVESTORS' EXCHANGE LLC

By: ____________________________

Name:

Title:

FINANCIAL INDUSTRY REGULATORY AUTHORITY, INC.

By: ____________________________

Name:

Title:

EXHIBIT 1

IEX CERTIFICATION OF COMMON RULES

IEX hereby certifies that the requirements contained in the rules listed below for IEX are identical to, or substantially similar to, the comparable FINRA (NASD) Rules, Exchange Act provision or SEC rule identified ("Common Rules").

IEX Rule	FINRA (NASD) Rule, exchange act provision, SEC Rule
Rule 2.140 Prohibited Conditions Relating to Expungement of Customer Dispute.	FINRA Rule 2081 Prohibited Conditions Relating to Expungement of Customer Dispute.
Rule 2.160(p) Restrictions on Membership—Continuing Education Requirements.	FINRA Rule 1250(a)(1)–(4) Continuing Education Requirements.[1]
Rule 2.170(b) and (g) Application Procedures for Membership or to become an Associated Person of a Member#.	FINRA By-Laws of the Corporation, Article IV, Section 1(c) Application for Membership.
Rule 2.240 Fidelity Bonds	FINRA Rule 4360 Fidelity Bonds.[2]
Rule 3.110 Business Conduct of Members^	FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade.^
Rule 3.120 Violations Prohibited[3]^	FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade^ and FINRA Rule 3110 Supervision.
Rule 3.130 Use of Fraudulent Devices^	FINRA Rule 2020 Use of Manipulative, Deceptive or Other Fraudulent Devices.^
Rule 3.150 Know Your Customer	FINRA Rule 2090 Know Your Customer.
Rule 3.160 Fair Dealing with Customers	FINRA Rule 2020 Use of Manipulative, Deceptive or Other Fraudulent Device.^
Rule 3.170 Suitability	FINRA Rule 2111 Suitability.
Rule 3.180(a) The Prompt Receipt and Delivery of Securities	FINRA Rule 11860 COD Orders.
Rule 3.180(b) The Prompt Receipt and Delivery of Securities	SEA Regulation SHO.
Rule 3.190 Charges for Services Performed	FINRA Rule 2122 Charges for Services Performed.
Rule 3.200 Use of Information Obtained in a Fiduciary Capacity	FINRA Rule 2060 Use of Information Obtained in Fiduciary Capacity.
Rule 3.210 Publication of Transactions and Quotations	FINRA Rule 5210 Publication of Transactions and Quotations.
Rule 3.220 Offers at Stated Prices	FINRA Rule 5220 Offers at Stated Prices.
Rule 3.230 Payments Involving Publications that Influence the Market Price of a Security.	FINRA Rule 5230 Payments Involving Publications that Influence the Market Price of a Security.
Rule 3.240 Customer Confirmations	FINRA Rule 2232(a) Customer Confirmations and SEC Rule 10b–10 Confirmation of Transactions.
Rule 3.250 Disclosure of Control Relationship with Issuer	FINRA Rule 2262 Disclosure of Control Relationship with Issuer.
Rule 3.260 Discretionary Accounts	NASD Rule 2510 Discretionary Accounts.
Rule 3.270 Improper Use of Customers' Securities or Funds; Prohibition Against Guarantees and Sharing in Accounts.	FINRA Rule 2150 Improper Use of Customers' Securities or Funds; Prohibition Against Guarantees and Sharing in Accounts.
Rule 3.280 Communications with the Public	FINRA Rule 2210 Communications with the Public.
Rule 3.290 Customer Disclosures	FINRA Rule 2265 Extended Hours Trading Risk Disclosure.
Rule 3.291 Influencing or Rewarding Employees of Others; Gratuities	FINRA Rule 3220 Influencing or Rewarding Employees of Others.
Rule 3.292 Telemarketing	FINRA Rule 3230 Telemarketing.
Rule 4.511 General Requirements	FINRA Rule 4511 General Requirements.
Rule 4.512 Customer Account Information	FINRA Rule 4512 Customer Account Information.
Rule 4.513 Record of Written Customer Complaints	FINRA Rule 4513 Record of Written Customer Complaints.
Rule 4.550 Disclosure of Financial Condition	FINRA Rule 2261 Disclosure of Financial Condition.
Rule 5.110 Supervision#	FINRA Rule 3110 Supervision.
Rule 5.120 Supervisory Control System	FINRA Rule 3120 Supervisory Control System.
Rule 5.130 Annual Certification of Compliance and Supervisory Processes.	FINRA Rule 3130 Annual Certification of Compliance and Supervisory Processes.
Rule 5.160 Anti-Money Laundering Compliance Program	FINRA Rule 3310 Anti-Money Laundering Compliance Program.
Rule 5.170 Transactions for or by Associated Persons	NASD Rule 3050 Transactions for or by Associated Persons.
Rule 6.120 Failure to Deliver and Failure to Receive	Regulation SHO Rules 200 and 203.
Rule 6.130(a), (b), (d) and (e) Forwarding of Proxy and Other Issuer-Related Materials; Proxy Voting.	FINRA Rule 2251 Forwarding of Proxy and Other Issuer-Related Materials.
Rule 10.110 Market Manipulation (except 10.110(b))	FINRA Rule 6140 Other Trading Practices.
Rule 10.110(b) Market Manipulation	FINRA Rule 5210 Publication of Transactions and Quotations, FINRA Rule 2020 Use of Manipulative, Deceptive or Other Fraudulent Devices, FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade, and FINRA Rule 6140(a) Other Trading Practices.
Rule 10.120 Fictitious Transactions	FINRA Rule 6140 Other Trading Practices and FINRA Rule 5210 Supplementary Material .02 Self-Trades.
Rule 10.130 Excessive Sales By A Member	FINRA Rule 6140 Other Trading Practices.
Rule 10.140 Manipulative Transactions	FINRA Rule 6140 Other Trading Practices.
Rule 10.150 Dissemination of False Information	FINRA Rule 6140 Other Trading Practices.
Rule 10.160 Prohibition Against Trading Ahead of Customer Orders.#**	FINRA Rule 5320 Prohibition Against Trading Ahead of Customer Orders.**
Rule 10.180 Influencing the Consolidated Tape	FINRA Rule 6140(a) Other Trading Practices.
Rule 10.190 Trade Shredding	FINRA Rule 5290 Order Entry and Execution Practices.
Rule 10.220 Best Execution and Interpositioning.**	FINRA Rule 5310 Best Execution and Interpositioning.**
Rule 10.240 Trading Ahead of Research Reports.**	FINRA Rule 5280 Trading Ahead of Research Reports.**
Rule 10.260 Front Running of Block Transactions	FINRA Rule 5270 Front Running of Block Transactions.
Rule 11.280(e)(3) & (4) Trading Halts Due to Extraordinary Market Volatility.	FINRA Rule 6190(a)(1) & (2) Compliance with Regulation NMS Plan to Address Extraordinary Market Volatility.
Rule 11.290 Short Sales[4]**	FINRA Rule 6182 Trade Reporting of Short Sales.**

[1] FINRA shall only have Regulatory Responsibilities to the extent the exercise of discretion by IEX is the same as FINRA.

[2] FINRA shall only have Regulatory Responsibilities to the extent any exemption by IEX is the same as FINRA.

[3] FINRA shall only have Regulatory Responsibilities regarding the first phrase of the IEX Rule regarding prohibitions from violating the Securities Exchange Act of 1934 and the rules and regulations thereunder; responsibility for the remainder of the rule shall remain with IEX.

[4] FINRA shall not have any Regulatory Responsibilities for Rule 11.290(b) through (d).

In addition, the following provisions shall be part of this 17d–2 Agreement:

Securities Exchange Act of 1934 ("SEA"):
Section 15(g)
SEA Rules:

- SEA Rule 200 of Regulation SHO—Definition of Short Sales and Marking Requirements**
- SEA Rule 201 of Regulation SHO—Circuit Breaker**
- SEA Rule 203 of Regulation SHO—Borrowing and Delivery Requirements**
- SEA Rule 204 of Regulation SHO—Close-Out Requirement**
- SEA Rule 101 of Regulation M—Activities by Distribution Participants
- SEA Rule 102 of Regulation M—Activities by Issuers and Selling Security Holders During a Distribution
- SEA Rule 103 of Regulation M—Nasdaq Passive Market Making
- SEA Rule 104 of Regulation M—Stabilizing and Other Activities in Connection with an Offering
- SEA Rule 105 of Regulation M—Short Selling in Connection With a Public Offering
- SEA Rule 10b–5 Employment of Manipulative and Deceptive Devices^
- SEA Rule 17a–3/17a–4—Records to Be Made by Certain Exchange Members, Brokers, and Dealers/Records to Be Preserved by Certain Exchange Members, Brokers, and Dealers^

FINRA shall not have Regulatory Responsibilities regarding notification or reporting to IEX.

^ FINRA shall not have any Regulatory Responsibilities for these rules as they pertain to violations of insider trading activities, which is covered by a separate 17d–2 Agreement by and among BATS Exchange, Inc., BATS–Y Exchange, Inc., Chicago Board Options Exchange, Incorporated, Chicago Stock Exchange, Inc., EDGA Exchange Inc., EDGX Exchange Inc., Financial Industry Regulatory Authority, Inc., NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, The NASDAQ Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange, LLC, NYSE Amex LLC, and NYSE Arca Inc. effective December 16, 2011, as may be amended from time to time.

** FINRA shall perform the surveillance responsibilities for the double star rules. These rules may be cited by FINRA in both the context of this Agreement and the Regulatory Services Agreement.

III. Date of Effectiveness of the Proposed Plan and Timing for Commission Action

Pursuant to Section 17(d)(1) of the Act[14] and Rule 17d–2 thereunder,[15] after July 20, 2016, the Commission may, by written notice, declare the plan submitted by IEX and FINRA, File No. 4–700, to be effective if the Commission finds that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among self-regulatory organizations, or to remove impediments to and foster the development of the national market system and a national system for the clearance and settlement of securities transactions and in conformity with the factors set forth in Section 17(d) of the Act.

IV. Solicitation of Comments

In order to assist the Commission in determining whether to approve the proposed 17d–2 Plan and to relieve IEX of the responsibilities which would be assigned to FINRA, interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number 4–700 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, Station Place, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number 4–700. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/other.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the plan also will be available for inspection and copying at the principal offices of IEX and FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number 4–700 and should be submitted on or before July 20, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2016–15757 Filed 7–1–16; 8:45 am]

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[14] 15 U.S.C. 78q(d)(1).

[15] 17 CFR 240.17d–2.

[16] 17 CFR 200.30–3(a)(34).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78188; File No. SR–NASDAQ–2016–082]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Listing and Trading of the Shares of the AdvisorShares Market Adaptive Unconstrained Income ETF of the AdvisorShares Trust

June 28, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 15, 2016, The Nasdaq Stock Market LLC ("Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes a rule change to the investment objective and the means of achieving the investment objective with respect to the AdvisorShares Market Adaptive Unconstrained Income ETF (the "Fund"), formerly known as the AdvisorShares Sunrise Global Multi-Strategy ETF. Shares of the Market Adaptive Unconstrained Income ETF are currently listed and traded on the Exchange"). The Fund is a series of AdvisorShares Trust (the "Trust"), under Nasdaq Rule 5735 ("Managed Fund Shares").[3] The shares of the Fund are collectively referred to herein as the "Shares."

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/,* at Nasdaq's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission has previously approved the listing and trading on the Exchange of Shares of the AdvisorShares Market Adaptive Unconstrained Income ETF (the "Fund"), formerly known as the AdvisorShares Sunrise Global Multi-Strategy ETF, a series of AdvisorShares Trust (the "Trust"), under Nasdaq Rule 5735 ("Managed Fund Shares").[4] The shares of the Fund are collectively referred to herein as the "Shares." Shares of the Fund are currently listed and traded on the Exchange.

The Shares are offered by the Trust, which is registered with the Commission as an open-end management investment company. The investment advisor to the Fund is AdvisorShares Investments, LLC (the "Adviser"). The sub-adviser for the Fund is American Wealth Management (the "Sub-Adviser"). The Adviser is not registered as a broker-dealer or affiliated with a broker-dealer. The Sub-advisor is registered as a broker dealer, but has implemented a "fire wall" between the investment adviser and the broker-dealer.

Paragraph (g) of Rule 5735 provides that if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect a "fire wall" between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[5] In addition, paragraph (g) further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the open-end fund's portfolio. Rule 5735(g) is similar to Nasdaq Rule 5705(b)(5)(A)(i); however, paragraph (g) in connection with the establishment of a "fire wall" between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. In the event (a) the Adviser or the Sub-Adviser becomes newly affiliated with a broker-dealer or registers as a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, if applicable, regarding access to information concerning the composition and/or changes to the portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

Under normal market conditions,[6] the Fund will seek to achieve its investment objective by investing at least 80% of its net assets in the principal investments as discussed below. In this proposed rule change, the Exchange proposes to reflect a change to the investment objective and the means that the Adviser will utilize to implement the Fund's investment objective. The Prior Release stated that the Fund's investment objective is to provide long-term total return by investing long and short in a variety of asset classes and investment strategies. The Adviser intends to revise the investment objective in the Prior Release to state that the Fund's investment objective will be to provide long-term total return and income with a secondary emphasis on capital preservation. The Prior Release further stated that the Fund, as part of its principal investments, will invest in exchange-traded funds ("ETFs") and other exchange-traded products, as well as U.S. treasuries, stock index futures, single stock futures, fixed income futures, currencies and currency futures.

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[3] The Commission approved Nasdaq Rule 5735 in Securities Exchange Act Release No. 57962 (June 13, 2008) 73 FR 35175 (June 20, 2008) (SR–NASDAQ–2008–039). There are already multiple actively-managed funds listed on the Exchange; *see* Securities Exchange Act Release No. 66489 (February 29, 2012), 77 FR 13379 (March 6, 2012) (SR–NASDAQ–2012–004) (order approving listing and trading of WisdomTree Emerging Markets Corporate Bond Fund). Additionally, the Commission has previously approved the listing and trading of a number of actively-managed WisdomTree funds on NYSE Arca, Inc. pursuant to Rule 8.600 of that exchange. *See, e.g.,* Securities Exchange Act Release No. 64643 (June 10, 2011), 76 FR 35062 (June 15, 2011) (SR–NYSEArca–2011–21) (order approving listing and trading of WisdomTree Global Real Return Fund). The Exchange believes the proposed rule change raises no significant issues not previously addressed in those prior Commission orders.

[4] *See* Securities Exchange Act Release No. 72426 (June 18, 2014), 79 FR 35825 (June 24, 2014) (SR–NASDAQ–2014–035) (order approving listing and trading of AdvisorShares Sunrise Global Multi-Strategy ETF, the "Prior Release").

[5] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the "Advisers Act"). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[6] The term "under normal market conditions" as used herein includes, but is not limited to, the absence of adverse market, economic, political or other conditions, including extreme volatility or trading halts in the securities markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or *force majeure* type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance. On a temporary basis, including for defensive purposes, during the initial invest-up period and during periods of high cash inflows or outflows, the Fund may depart from its principal investment strategies; for example, it may hold a higher than normal proportion of its assets in cash. During such periods, the Fund may not be able to achieve its investment objective. The Fund may adopt a defensive strategy when the Adviser and/or the Sub-Adviser believes securities in which the Fund normally invests have elevated risks due to political or economic factors and in other extraordinary circumstances.

The Adviser proposes to revise the representations as stated in the Prior Release to now state that the Fund, as part of its principal investments, will invest in exchange-traded funds and other exchange-traded products including but not limited to, exchange-traded notes ("ETNs"), and closed-end funds (together with ETFs, "ETPs"). The Adviser also proposes to revise the representations in the Prior Release and state that the Fund may now only invest in U.S. treasuries, stock index futures, single stock futures, fixed income futures, currencies, and currency futures as "other investments," up to a maximum of 20% of the Fund's net assets, and no longer as part of the principal investment strategy.

2. Statutory Basis

Nasdaq believes that the proposal is consistent with Section 6(b) of the Act, in general, and Section 6(b)(5) of the Act, in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and in general, to protect investors and the public interest. The Fund will continue to comply with all the initial and continued listing requirements under Nasdaq Rule 5735.

The Exchange proposes that the Fund be permitted to amend its investment objective to state that the Fund will invest in ETPs, which will better-define the objective of the Fund. The Adviser represents that U.S. treasuries, stock index futures, single stock futures, fixed income futures, currencies, and currency futures will no longer be part of the principal investment strategy, and will only be permitted as "other investments," up to a maximum of 20% of the Fund's net assets. Except for the changes noted above, all other representations made in the Prior Release remain unchanged.

For the above reasons, Nasdaq believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed rule change will accommodate continued listing and trading of Managed Fund Shares and will permit the Adviser additional flexibility in achieving the Fund's investment objectives.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and subparagraph (f)(6) of Rule 19b–4 thereunder.[8]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2016–082 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–082. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–082 and should be submitted on or before July 26, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–15761 Filed 7–1–16; 8:45 am]

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[7] 15 U.S.C. 78s(b)(3)(a)(iii).

[8] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78187; File No. SR–C2–2016–009]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Professionals Order Counting

June 28, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 23, 2016, C2 Options Exchange, Incorporated (the "Exchange" or "C2") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its definition of "Professional" in Rule 1.1 to include guidance on how orders should be counted for Professional order counting purposes. The text of the proposed rule change is provided below (additions are *italicized;* deletions are [bracketed]).

* * * * *

C2 Options Exchange, Incorporated

Rules

* * * * *

CHAPTER 1

Definitions

Rule 1.1. Definitions

* * * * *

Professional

The term "Professional" means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). A Professional will be treated in the same manner as a broker or dealer in securities for purposes of Rules 6.11, 6.12, 6.13(b)(1), 6.13(c)(5), 6.14, 6.15, 6.51, 6.52 and 8.13. *All Professional orders shall be marked with the appropriate origin code as determined by the Exchange.*

. . . *Interpretations and Policies:*

.01 Except as noted below, each order of any order type counts as one order for Professional order counting purposes.

(a) Complex Orders:

(1) A complex order comprised of eight (8) legs or fewer counts as a single order.

(2) A complex order comprised of nine (9) legs or more counts as multiple orders with each option leg counting as its own separate order.

(b) "Parent"/"Child" Orders:

(1) Same Side and Same Series: A "parent" order that is placed for the beneficial account(s) of a person or entity that is not a broker or dealer in securities that is broken into multiple "child" orders on the same side (buy/sell) and series as the "parent" order by a broker or dealer, or by an algorithm housed at a broker or dealer or by an algorithm licensed from a broker or dealer, but which is housed with the customer, counts as one order even if the "child" orders are routed across multiple exchanges.

(2) Both Sides and/or Multiple Series: A "parent" order (including a strategy order) that is broken into multiple "child" orders on both sides (buy/sell) of a series and/or multiple series counts as multiple orders, with each "child" order counting as a new and separate order.

(c) Cancel/Replace:

(1) Except as provided in paragraph (c)(2) below, any order that cancels and replaces an existing order counts as a separate order (or multiple new orders in the case of a complex order comprised of nine (9) legs or more).

(2) Same Side and Same Series: An order that cancels and replaces any "child" order resulting from a "parent" order that is placed for the beneficial account(s) of a person or entity that is not a broker, or dealer in securities that is broken into multiple "child" orders on the same side (buy/sell) and series as the "parent" order by a broker or dealer, by an algorithm housed at a broker or dealer, or by an algorithm licensed from a broker or dealer, but which is housed with the customer, does not count as a new order.

(3) Both Sides and/or Multiple Series: An order that cancels and replaces any "child" order resulting from a "parent" order (including a strategy order) that generates "child" orders on both sides (buy/sell) of a series and/or in multiple series counts as a new order.

(4) Pegged Orders: Notwithstanding the provisions of paragraph (c)(2) above, an order that cancels and replaces any "child" order resulting from a "parent" order being "pegged" to the BBO or NBBO or that cancels and replaces any "child" order pursuant to an algorithm that uses BBO or NBBO in the calculation of "child" orders and attempts to move with or follow the BBO or NBBO of a series counts as a new order each time the order cancels and replaces in order to attempt to move with or follow the BBO or NBBO.

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its definition of "Professional" in Rule 1.1 to include guidance on how orders should be counted for Professional order counting purposes. Specifically, the Exchange proposes to adopt Interpretation and Policy .01 to the definition of "Professional" within Rule 1.1 (Definitions), setting forth standards for calculating average daily order submissions for Professional order counting purposes. The Exchange also proposes to add a provision to Rule 1.1's definition of Professional, which would provide that all Professional orders shall be marked with the appropriate origin code as determined by the Exchange. The Exchange believes that the proposed rule change would provide additional clarity in the Rules and serve to promote the purposes for which the

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

Exchange's Professional rule was originally adopted. The Exchange notes that this filing is materially based upon and substantially similar to rule changes recently adopted by several of the U.S. options exchanges, including, but not limited to Chicago Board Options Exchange, Incorporated (''CBOE'') filing SR–CBOE–2016–005.[5]

Background

In general, ''public customers'' are granted certain marketplace advantages over other market participants, including Market-Makers, brokers and dealers of securities, and industry ''Professionals'' on most U.S. options exchanges. The U.S. options exchanges, including C2, have adopted materially similar definitions of the term ''Professional,''[6] which commonly refers to persons or entities that are not a brokers or dealers in securities and who or which place more than 390 orders in listed options per day on average during a calendar month for their own beneficial account(s).[7] Various exchanges adopted similar Professional rules for many of the same reasons, including, but not limited to the desire to create more competitive marketplaces and attract retail order flow.[8] In addition, as several of the exchanges noted in their original Professional rule filings, their beliefs that disparate Professional rules and a lack of uniformity in the application of such rules across the options markets would not promote the best regulation and may, in fact, encourage regulatory arbitrage.[9]

Similar to other U.S. options exchanges, the Exchange grants ''public customers'' certain marketplace advantages over other market participants pursuant to the Exchange's Fees Schedule[10] and the Rules.[11] In general, public customers may receive allocation and execution priority above equally priced competing interests of Market-Makers, broker-dealers, and other market participants. In addition, customer orders may be exempt or pay lower transaction fees and/or be exempt from certain Exchange surcharges. Similar to other U.S. options exchanges, the Exchange affords these marketplace advantages to public customers based on various business- and regulatory-related objectives, including, for example, to attract retail order flow to the Exchange and to provide competitive pricing.

Currently, Rule 1.1 defines a Professional as a person or entity that is not a securities broker or dealer that places more than 390 listed options orders per day on average during a calendar month for its own beneficial account(s). In large part, the Exchange's Professional order rules were adopted to distinguish non-broker dealer individuals and entities that have access to information and technology that enable them to professionally trade listed options in a manner similar to brokers or dealers in securities from retail investors for order priority and/or transaction fees purposes. In general, Professionals are treated as brokers or dealers in securities under the Exchange's rules, including, but not limited to with respect to order priority and fees.[12] Rule 1.1 is substantially similar to the Professional order rules of other exchanges and was materially based upon the preexistent Professional order rules of other exchanges.[13]

Over time, the Exchange has received various questions as to what constitutes an ''order'' for Professional order counting purposes, including, but not limited to questions about how to count certain types of strategy orders and how to count ''child'' orders generated as part of specific ''parent'' execution strategies. The advent of new multi-leg spread products and the proliferation of the use of complex orders and algorithmic execution strategies by both institutional and retail market participants have continued to spur questions as to what constitutes an ''order'' for Professional order counting purposes. For example, do multi-leg spread orders or strategy orders such as volatility orders constitute a single order or multiple orders for Professional order counting purposes? The Exchange's

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[5] *See* Securities Exchange Act Release No. 77450 (March 25, 2016), 81 FR 18668 (March 31, 2016) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Interpretation and Policy .01 to Rule 1.1(ggg) Relating to the Professional Customer Definition) (SR–CBOE–2016–005); Securities Exchange Act Release No. 77449 (March 25, 2016), 81 FR 18665 (March 31, 2016) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Professional Customer Definition) (SR–Phlx–2016–10); Securities Exchange Act Release No. 77580 (April 11, 2016), 81 FR 22328 (April 15, 2016) (Notice of Filing of Proposal to Amend Rule 100 (Definitions) Relating to Professionals) (SR–BOX–2016–13); *see also* Securities Exchange Act Release No. 73628 (November 18, 2014), 79 FR 69958 (November 24, 2014) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Professional Orders) (SR–CBOE–2014–085).

[6] Some U.S. options exchanges refer to ''Professionals'' as ''Professional Customers'' or non-''Priority Customers.'' *Compare* BATS Exchange, Inc. (''BZX'') Rule 16.1(a)(45) (Professional); BOX Options Exchange LLC (''BOX'') Rule 100(a)(50) (Professional); CBOE Rule 1.1(ggg) (Professional); C2 Rule 1.1; BX Chapter I, Sec. 1(49) (Professional); NASDAQ OMX PHLX LLC (''PHLX'') Rule 1000(b)(14) (Professional); Nasdaq Options Market (''NOM'') Chapter I, Sec. 1(a)(48) (Professional); *with* ISE Rule 100(a)(37A) (Priority Customer); Gemini Rule 100(a)(37A) (Priority Customer); Miami International Securities Exchange LLC (''MIAX'') Rule 100 (Priority Customer); NYSE MKT LLC (''NYSE MKT'') Rule 900.2NY(18A) (Professional Customer); NYSE Arca, Inc. (''Arca'') Rule 6.1A(4A) (Professional Customer).

[7] *See, e.g.,* BZX Rule 16.1(a)(45); BOX Rule 100(a)(50); CBOE Rule 1.1(ggg); C2 Rule 1.1; BX Chapter I, Sec. 1(49); PHLX Rule 1000(b)(14); NOM Chapter I, Sec. 1(a)(48); *see also* ISE Rule 100(a)(37A) (Priority Customer); Gemini Rule 100(a)(37A) (Priority Customer); MIAX Rule 100 (Priority Customer); NYSE MKT Rule 900.2NY(18A) (Professional Customer); Arca Rule 6.1A(4A) (Professional Customer).

[8] *See, e.g.,* Securities Exchange Act Release No. 60931 (November 4, 2009), 74 FR 58355, 58356 (November 12, 2009) (Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 1, Related to Professional Orders) (SR–CBOE 2009–078); Securities Exchange Act Release No. 59287 (January 23, 2009), 74 FR 5694, 5694 (January 30, 2009) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of the Proposed Rule Change, as Modified by Amendment Nos. 1 and 2 Thereto, Relating to Professional Account Holders) (SR–ISE–2006–026); Securities Exchange Act Release No. 61802 (March 30, 2010), 75 FR 17193, 17194 (April 5, 2010) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of the Proposed Rule Change, as Modified by Amendment No. 2 Thereto, Relating to Professional Orders) (SR–PHLX–2010–005); Securities Exchange Act Release No. 61629 (March 2, 2010), 75 FR 10851, 10851 (March 9, 2010) (Notice of Filing of Proposed Rule Change Relating to the Designation of a ''Professional Customer'') (SR–NYSEMKT–2010–018).

[9] *See, e.g.,* Securities and Exchange Act Release No. 62724 (August 16, 2010), 75 FR 51509 (August 20, 2010) (Notice of Filing of a Proposed Rule Change by the NASDAQ Stock Market LLC To Adopt a Definition of Professional and Require That All Professional Orders Be Appropriately Marked) (SR–NASDAQ–2010–099); Securities and Exchange Act Release No. 65500 (October 6, 2011), 76 FR 63686 (October 13, 2011) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a Definition of Professional and Require That All Professional Orders Be Appropriately Marked) (SR–BATS–2011–041); Securities Exchange Act Release No. 65036 (August 4, 2011), 76 FR 49517, 49518 (August 10, 2011) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a Definition of ''Professional'' and Require That Professional Orders Be Appropriately Marked by BOX Options Participants) (SR–BX–2011–049); Securities Exchange Act Release No. 60931 (November 4, 2009), 74 FR 58355, 58357 (November 12, 2009) (Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 1, Related to Professional Orders) (SR–CBOE 2009–078); *see also* Securities Exchange Act Release 73628 (November 18, 2014), 79 FR 69958, 69960 (November 24, 2014) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Professional Orders) (SR–CBOE–2014–085).

[10] *See, e.g.,* Fees Schedule (Transaction Fees).

[11] *See, e.g.,* Rules 6.12(c) (Order Execution and Priority—Contingency Orders); 6.13(c)(5)(B) (Complex Order Execution—Execution of COA-Eligible Orders); 6.51(b)(3) (Automated Improvement Mechanism (''AIM'')—Order Allocation).

[12] *See* Rule 1.1; Fees Schedule (Transaction Fees).

[13] *See* Securities Exchange Act Release No. 60931 (November 4, 2009), 74 FR 58355, 58356 (November 12, 2009) (Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 1, Related to Professional Orders) (SR–CBOE 2009–078); *see, e.g.,* ISE Rule 100(a)(31A).

Professional rule does not fully address these issues and, to date, there has not been a common interpretation across the U.S. options markets. The Exchange believes that additional clarity is needed regarding the application of Rule 1.1 with respect to Professionals. Accordingly, the Exchange is proposing to amend Rule 1.1 to add Interpretation and Policy .01 to the definition of Professional to address how various new execution and order strategies should be treated under the Exchange's Professional rule. The Exchange believes that the adoption of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional is warranted to ensure that public customers are afforded the marketplace advantages that they are intended to be afforded over other types of market participants on the Exchange.

The Exchange notes that despite the adoption of materially similar Professional rules across the markets, exchanges' interpretations of their respective Professional rules vary. Although Professionals are similarly defined by exchanges as non-broker-dealer persons or entities that place more than 390 orders in listed options for their own beneficial account(s) per day on average during a calendar month, there is no consistent definition across the markets as to what constitutes an "order" for Professional order counting purposes. While several options exchanges have attempted to clarify their interpretations of their Professional rules through regulatory and information notices and circulars,[14] those interpretations have not necessarily been consistent.[15] As a result, the Exchange believes that the rather than helping to promote the best regulation and discourage regulatory arbitrage, the Professional rules have become a basis of intermarket competition. The Exchange believes that the proposed set of standards would allow the Exchange to better compete for order flow and help ensure deeper levels of liquidity on the Exchange. The Exchange also believes that the proposed rule change would help to remove impediments to and help perfect the mechanism of a free and open market and a national market system by increasing competition in the marketplace. Accordingly, the Exchange proposes to amend the Rules by adopting Interpretation and Policy .01 to Rule 1.1's definition of Professional.

Proposal

The Exchange proposes to adopt Interpretation and Policy to Rule 1.1's definition of Professional setting forth a detailed counting regime for calculating average daily orders for Professional order counting purposes. Specifically, the Exchange's proposed Interpretation and Policy would make clear how to count complex orders, "parent/child" orders that are broken into multiple orders, and "cancel/replace" orders for Professional order counting purposes.

Under the Exchange's proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, all orders would count as one single order for Professional counting purposes, unless otherwise specified under the Rules. Proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would provide that except as noted below, each order of any order type counts as one order for Professional order counting purposes. Paragraph (a) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would discuss complex orders. Under paragraph (a)(1) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, a complex order comprised of eight (8) legs or fewer would count as a single order. Conversely, paragraph (a)(2) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would provide that a complex order comprised of nine (9) legs or more counts as multiple orders with each option leg counting as its own separate order. The Exchange believes the distinction between complex orders with up to eight legs from those with nine or more legs is appropriate in light of the purposes for which the Exchange's Professional rule was adopted. In particular, the Exchange notes that multi-leg complex order strategies with nine or more legs are more complex in nature and thus, more likely to be used by professional traders than traditional two, three, and four leg complex order strategies such as the strangle, straddle, butterfly, collar, condor strategies, and combinations thereof with eight legs or fewer, which are generally not algorithmically generated and are frequently used by retail investors. Thus, the types of complex orders traditionally placed by retail investors would continue to count as only one order while the more complex strategy orders that are typically used by professional traders would count as multiple orders for Professional order counting purposes.

Paragraph (b) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would provide details relating to the counting of "parent/child" orders. Under paragraph (b)(1) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, a "parent" order that is placed for the beneficial account(s) of a person or entity that is not a broker or dealer in securities that is broken into multiple "child" orders on the same side (buy/sell) and series as the "parent" order by a broker or dealer, or by an algorithm housed at a broker or dealer or by an algorithm licensed from a broker or dealer, but which is housed with the customer, counts as one order even if the "child" orders are routed across multiple exchanges. Essentially, this paragraph would describe how orders placed for public customers, which are "worked" by a broker in order to receive best execution should be counted for Professional order counting purposes. Paragraph (b)(1) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would permit larger "parent" orders (which may be simple orders or complex orders consisting of up to eight legs), to be broken into multiple smaller orders on the same side (buy/sell) and in the same series (or complex orders consisting of up to eight legs) in order to attempt to achieve best execution for the overall order.

For example, if a customer were to enter an order to buy 1,000 XYZ $5 January calls at a limit price of $1, which the customer's broker then broke into four separate orders to buy 250 XYZ $5 January calls at a limit price of $1 in order to achieve a better execution, the four "child" orders would still only count as one order for Professional order counting purposes (whether or not the four separate orders were sent to the same or different exchanges for execution).[16] Similarly, in

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[14] *See* Regulatory Circular RG09–148 (Professional Orders); ISE Regulatory Information Circular 2014–007/Gemini Regulatory Information Circular 2014–011 (Priority Customer Orders and Professional Orders (FAQ)); MIAX Regulatory Circular 2014–69 (Priority Customer and Professional Interest Order Summary); NYSE Joint Regulatory Bulletin, NYSE Acra RBO–15–03, NYSE Amex RBO–15–06) (Professional Customer Orders); BOX Regulatory Circular RC–2015–21 (Professional Orders).

[15] *Compare* NYSE Joint Regulatory Bulletin, NYSE Acra RBO–15–03, NYSE Amex RBO–15–06) (Professional Customer Orders); Interpretation and Policy .01 to Rule 1.1(ggg) *with* ISE Regulatory Information Circular 2014–007/Gemini Regulatory Information Circular 2014–011 (Priority Customer Orders and Professional Orders (FAQ)); and ISE Regulatory Information Circular 2009–179 (Priority Customer Orders and Professional Orders (FAQ)).

[16] Notably, however, if the customer herself were to enter the same four identical orders to buy 250 XYZ $5 January calls at a limit price of $1 prior to sending the orders, those orders would count as four separate orders for Professional order counting purposes because the orders would not have been broken into multiple "child" orders on the same

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the case of a complex order, if a customer were to enter an order to buy 1,000 XYZ $5 January(sell)/March(buy) calendar spreads (with a 1:1 ratio on the legs), at a net debit limit price of $0.20, which the customer's broker then broke into four separate orders to buy 250 XYZ $5 January/March calendar spreads (each with a 1:1 ratio on the legs), each at a net debit limit price of $0.20, the four "child" orders would still only count as one order for Professional order counting purposes (whether or not the four separate orders were sent to the same or different exchanges for execution).

Conversely, under paragraph (b)(2) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, a "parent" order (including a strategy order)[17] that is broken into multiple "child" orders on both sides (buy/sell) of a series and/or multiple series counts as multiple orders, with each "child" order counting as a new and separate order. Accordingly, under this provision, strategy orders, which are most often used by sophisticated traders best characterized as "Professionals," would count as multiple orders for each child order entered as part of the overall strategy. For example, if a customer were to enter a volatility order[18] or "vega" order[19] with her broker by which multiple "child" orders were then sent to the Exchange across multiple series in a particular option class, each order entered would count as a separate order for Professional order counting purposes. Likewise, if the customer instructed her broker to buy a variety of calls across various option classes as part of a basket trade, each order entered by the broker in order to obtain the positions making up the basket would count as a separate order for Professional counting purposes.[20]

The Exchange believes that the distinctions between "parent" and "child" orders in paragraph (b) to proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional are appropriate. The Exchange notes that paragraph (b) to proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional is not aimed at capturing orders that are being "worked" or broken into multiple orders to avoid showing large orders to the market in an effort to elude front-running and to achieve best execution as is typically done by brokers on behalf of retail clients. Rather, paragraph (b) to proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional is aimed at identifying "child" orders of "parent" orders generated by algorithms that are typically used by sophisticated traders to continuously update their orders in concert with market updates in order to keep their overall trading strategies in balance. The Exchange believes that these types of "parent/child" orders typically used by sophisticated traders should count as multiple orders.

Paragraph (c) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, would discuss the counting of orders that are cancelled and replaced. Similar to the distinctions drawn in paragraph (b) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, paragraph (c) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would essentially separate orders that are cancelled and replaced as part of an overall strategy from those that are cancelled and replaced by a broker that is "working" the order to achieve best execution or attempting to time the market. Specifically, paragraph (c)(1) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would provide that except as otherwise provided in the rule (and specifically as provided under paragraph (c)(2) to proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional), any order that cancels and replaces an existing order counts as a separate order (or multiple new orders in the case of a complex order comprised of nine (9) legs or more). For example, if a trader were to enter a non-marketable limit order to buy an option contract at a certain net debit price, cancel the order in response to market movements, and then reenter the same order once it became marketable, those orders would count as two separate orders for Professional order counting purposes even though the terms of both orders were the same.

Paragraph (c)(2) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would specify the exception to paragraph (c)(1) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional and would provide that an order that cancels and replaces any "child" order resulting from a "parent" order that is placed for the beneficial account(s) of a person or entity that is not a broker, or dealer in securities that is broken into multiple "child" orders on the same side (buy/sell) and series as the "parent" order by a broker or dealer, by an algorithm housed at a broker or dealer, or by an algorithm licensed from a broker or dealer, but which is housed with the customer, would not count as a new order. For example, if a customer were to enter an order with her broker to buy 10,000 XYZ $5 January calls at a limit price of $1, which the customer's broker then entered, but could not fill and then cancelled to avoid having to rest the order in the book as part of a strategy to obtain a better execution for the customer and then resubmitted the remainder of the order, which would be considered a "child" of the "parent" order, once it became marketable, such orders would only count as one order for Professional order counting purposes. Again, similar to paragraph (b) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, the Exchange notes that paragraph (c) to proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional is not aimed at capturing orders that are being "worked" or being cancelled and replaced to avoid showing large orders to the market in an effort to elude front-running and to achieve best execution as is typically done by brokers on behalf of retail clients. Rather, paragraph (c) to proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional is

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side (buy/sell) and series as the "parent" order by a broker or dealer, or by an algorithm housed at a broker or dealer or by an algorithm licensed from a broker or dealer, but which is housed with the customer.

[17] For purposes of this proposed Interpretation and Policy, the term "strategy order" is intended to mean an execution strategy, trading instruction, or algorithm whereby multiple "child" orders on both sides of a series and/or multiple series are generated prior to being sent to any or multiple U.S. options exchange(s).

[18] A "volatility" or "volatility-type" order may be characterized as an order instruction or combination to buy/sell contracts at a specific implied volatility rather than at a specific price or premium. Because implied volatility is a key determinant of the premium on an option, some traders may wish to take positions in specific contract months in an effort to take advantage of perceived changes in implied volatility arising before, during, or after earnings or in a certain company when specific or broad market volatility is predicted to change. In certain cases, depending on where a customer's account is housed or the trading capabilities of the participant involved, an options trader may trade and position for movements in the price of the option based on implied volatility using a "volatility" or "volatility-type" order or trading instruction by setting a limit for the volatility level they are willing to pay or receive. In such cases, premiums may be calculated in percentage terms rather than premiums.

[19] An option's vega is a measure of the impact of changes in the underlying volatility on the option price. Specifically, the vega of an option expresses the change in the price of the option for every 1% change in underlying volatility.

[20] Notably, with respect to the types of "parent" orders (including strategy orders) described in paragraph (b)(2) to proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, such orders would be received only as multiple "child" orders the U.S. options exchange receiving such orders. The "parent" order would be broken apart before being sent by the participant to the exchange(s) as multiple "child" orders. *See supra* at note 17.

aimed at identifying "child" orders of "parent" orders generated by algorithms that are typically used by sophisticated traders to continuously update their orders in concert with market updates in order to keep their overall trading strategies in balance. The Exchange believes that paragraph (c)(2) to proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional is consistent with these goals.

Accordingly, consistent with paragraph (c)(1) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, under paragraph (c)(3) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional, an order that cancels and replaces any "child" order resulting from a "parent" order (including a strategy order) that generates "child" orders on both sides (buy/sell) of a series and/or in multiple series would count as a new order. For example, if an investor were to seek to make a trade (or series of trades) to take a long vega position at a certain percentage limit on a basket of options, the investor may need to cancel and replace several of the "child" orders entered to achieve the overall execution strategy several times to account for updates in the prices of the underlyings. In such a case, each "child" order placed to keep the overall execution strategy in place would count as a new and separate order even if the particular "child" order were being used to replace a slightly different "child" order that was previously being used to keep the same overall execution strategy in place. The Exchange believes that the distinctions between cancel/replace orders in paragraph (c) to proposed Rule 1.1's definition of Professional are appropriate as such orders are typically generated by algorithms used by sophisticated traders to keep strategy orders continuously in line with updates in the markets. As such, the Exchange believes that in most cases, cancel/replace orders should count as multiple orders.

Paragraph (c)(4) of proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would provide that notwithstanding the provisions of paragraph (c)(2) above, an order that cancels and replaces any "child" order resulting from a "parent" order being "pegged" to the Exchange's best bid or offer ("BBO") or national best bid or offer ("NBBO") or that cancels and replaces any "child" order pursuant to an algorithm that uses BBO or NBBO in the calculation of "child" orders and attempts to move with or follow the BBO or NBBO of a series would count as a new order each time the order cancels and replaces in order to attempt to move with or follow the BBO or NBBO. The Exchange believes that paragraph (c)(4) is appropriate to make clear that "pegged" strategy orders that are typically used by sophisticated traders should be counted as multiple orders even though such orders may cancel/replace orders in on the same side (buy/sell) of the market in a single series in order to achieve an overall order strategy.

Finally, the Exchange also proposes to amend Rule 1.1 to provide that all Professional orders shall be marked with the appropriate origin code as determined by the Exchange in order to bring the Exchange's rules in-line with the Professional order rules of other exchanges.[21] The Exchange notes that Permit Holders are already required to mark orders with appropriate origin codes.[22] The Exchange is simply proposing to codify this requirement in the Rules under the definition of Professional in current Rule 1.1; Permit Holders would continue to be required to indicate whether public customer orders are "Professional" orders as they are currently. To comply with this requirement, Permit Holders would be required to review their customers' activity on at least a quarterly basis to determine whether orders that are not for the account of a broker or dealer should be represented as customer orders or Professional orders and make any appropriate changes to the way in which they are representing orders within five days after the end of each calendar quarter. Orders for any customer that had an average of more than 390 orders per day during any month of a calendar quarter must be represented as Professional orders for the next calendar quarter. If, however, during a quarter the Exchange identifies a customer for which orders are being represented as public customer orders but that has averaged more than 390 orders per day during a month, the Exchange will notify the Permit Holder and the Permit Holder will be required to change the manner in which it is representing the customer's orders within five days.

Because the rule only requires that Permit Holders conduct a look-back to determine whether their customers are averaging more than 390 orders per day at the end of each calendar quarter, the Exchange proposes an effective date of July 1, 2016 for proposed Interpretation and Policy .01 to the definition of Professional in Rule 1.1 to ensure that all orders during the next quarterly review will be counted in the same manner and that proposed Interpretation and Policy .01 to Rule 1.1(ggg) [sic] will not be applied retroactively.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[23] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [24] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[25] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional provides a more conservative order counting regime for Professional order counting purposes that would identify more traders as Professionals to which the Exchange's definition of Professional was designed to apply and create a better competitive balance for all participants on the Exchange, consistent with the Act. As the options markets have evolved to become more electronic and more competitive, the Exchange believes that the distinction between registered broker-dealers and professional traders who are currently treated as public customers has become increasingly blurred. More and more, the category of public customer today includes sophisticated algorithmic traders including former market makers and hedge funds that trade with a frequency resembling that of broker-dealers. The Exchange believes that it is reasonable under the Act to treat those customers who meet the high level of trading activity established in the proposal differently than customers who do not meet that threshold and are more typical retail investors to ensure that professional traders do not take advantage of priority and fee benefits intended for public customers.

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[21] *See* see [sic] also Securities Exchange Act Release No. 73628 (November 18, 2014), 79 FR 69958 (November 24, 2014) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Professional Orders) (SR–CBOE–2014–085); *see also* ISE Regulatory Information Circular 2014–007 (Priority Customer Orders and Professional Orders (FAQ)).

[22] *See* Regulator Circular C2 RG13–015 (Order Origin Requirement).

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

[25] *Id.*

The Exchange notes that it is not unfair to differentiate between different types of investors in order to achieve certain marketplace balances. The Rules currently differentiate between public customers, broker-dealers, Market-Makers, and the like. These differentiations have been recognized to be consistent with the Act. The Exchange does not believe that the current rules of C2 or other exchanges that accord priority to all public customers over broker-dealers are unfairly discriminatory. Nor does the Exchange believe that it is unfairly discriminatory to accord priority to only those customers who on average do not place more than one order per minute (390 per day) under the counting regime that the Exchange proposes. The Exchange believes that such differentiations drive competition in the marketplace and are within the business judgment of the Exchange. Accordingly, the Exchange also believes that its proposal is consistent with the requirement of Section 6(b)(8) of the Act that the rules of an exchange not impose an unnecessary or inappropriate burden upon competition in that it treats persons who should be deemed Professionals (but who may not be under the current Rules), in a manner so that they do not receive special priority benefits.

Furthermore, the Exchange believes that the proposed rule change will protect investors and the public interest by helping to assure that retail customers continue to receive the appropriate marketplace advantages in the C2 marketplace as intended, while furthering competition among marketplace professionals by treating them in the same manner as other similarly situated market participants. The Exchange believes that it is consistent with Section 6(b)(5) of the Act not to afford market participants with similar access to information and technology as that of brokers and dealers of securities with marketplace advantages over such marketplace competitors. The Exchange also believes that the proposed Interpretation and Policy would help to remove burdens on competition and promote a more competitive marketplace by affording certain marketplace advantages only to those for whom they are intended. The Exchange believes that the proposed rule change sets forth a more detailed and clear regulatory regime with respect to calculating average daily order entry for Professional order counting purposes. The Exchange believes that this additional clarity and detail will eliminate confusion among market participants, which is in the interests of all investors and the general public. The Exchange also believes that codifying the requirement that all Professional orders shall be marked with the appropriate origin code as determined by the Exchange will add additional transparency and clarity to the Rules, which is also in the interests of all investors and the general public.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the Exchange does not believe that the current rules of C2 and other exchanges that accord priority to all public customers over broker-dealers are unfairly discriminatory. Nor does the Exchange believe that it is unfairly discriminatory to accord priority to only those customers who on average do not place more than one order per minute (390 per day) under the counting regime that the Exchange proposes. The Exchange believes that its proposal does not impose an undue burden on competition. The Exchange notes that one of the purposes of the Professional rules is to help ensure fairness in the marketplace and promote competition among all market participants. The Exchange believes that proposed Interpretation and Policy .01 to Rule 1.1's definition of Professional would help establish more competition among market participants and promote the purposes for which the Exchange's Professional rule was originally adopted. The Exchange does not believe that the Act requires it to provide the same incentives and discounts to all market participants equally, so as long as the exchange does not unfairly discriminate among participants with regard to access to exchange systems. The Exchange believes that here, that is clearly the case.

Rather than burden competition, the Exchange believes that the proposed rule change promotes competition by ensuring that retail investors continue to receive the appropriate marketplace advantages in the C2 marketplace as intended, while furthering competition among marketplace professionals by treating them in the same manner under the Rules as other similarly situated market participants by ensuring that market participants with similar access to information and technology (*i.e.* Professionals and broker-dealers), receive similar treatment under the Rules while retail investors receive the benefits of order priority and fee waivers that are intended to apply to public customers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[26] and subparagraph (f)(6) of Rule 19b–4 thereunder.[27] A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing.[28] Rule 19b–4(f)(6)(iii), however, permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest.[29]

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission notes that it has considered substantially similar proposed rule changes filed by CBOE and PHLX which it approved after a notice and comment period.[30] This proposed rule change does not raise any new or novel issues from those considered in the CBOE or PHLX proposals. Based on the foregoing, the Commission believes that it is consistent with the protection of investors and the public interest to waive the 30-day operative date so that the proposal may take effect upon filing.[31]

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[26] 15 U.S.C. 78s(b)(3)(a)(iii).

[27] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[28] 17 CFR 240.19b–4(f)(6)(iii).

[29] *Id.*

[30] *See* Securities Exchange Act Release Nos. 77450 (March 25, 2016) (Order Approving SR–CBOE–2016–005); 77449 (March 25, 2016), 81 FR 18665, (March 31, 2016) (Order Approving SR–Phlx–2016–10).

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) of the Act[32] to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–C2–2016–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–C2–2016–009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–C2–2016–009, and should be submitted on or before July 26, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–15760 Filed 7–1–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78186; File No. SR–MSRB–2016–08]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Content Outline for the Municipal Advisor Representative Qualification Examination (Series 50)

June 28, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act" or "Exchange Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 15, 2016 the Municipal Securities Rulemaking Board (the "MSRB" or "Board") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the MSRB. The MSRB has designated the proposed rule change as "constituting a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule" under Section 19(b)(3)(A)(i) of the Act[3] and Rule 19b–4(f)(1) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission.[5] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB filed with the Commission proposed revisions to the content outline for the Municipal Advisor Representative Qualification Examination (Series 50) (the "proposed rule change"). The MSRB proposes to implement the revised Series 50 examination program on September 12, 2016. The proposed revisions to the content outline update the material to reflect changes to the laws, rules and regulations covered by the examination and to incorporate the functions and associated tasks currently performed by a Municipal Advisor Representative. As a result of recent changes to MSRB rules, revisions to the Series 50 content outline are necessary to indicate the current rule requirements and rule citations. In addition, the Board is proposing to make changes to the format of the content outline. The MSRB is not proposing in this filing any textual changes to its rules.

The text of the proposed rule change is available on the MSRB's Web site at *www.msrb.org/Rules-and-Interpretations/SEC-Filings/2016-Filings.aspx,* at the MSRB's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The MSRB has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

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[31] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[32] 15 U.S.C. 78s(b)(2)(B).

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(i).

[4] 17 CFR 240.19b–4(f)(1).

[5] *See also* letter to Diane G. Klinke, General Counsel, MSRB, from Belinda Blaine, Associate Director, Division of Market Regulation, SEC, dated July 24, 2000, attached as Exhibit 3b.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 15B(b)(2)(L)(iii) of the Act requires the MSRB to establish professional standards for municipal advisors.[6] The Act further requires associated persons of municipal advisors to pass such examinations as the Board may establish to demonstrate that such individuals meet the standards as the Board finds necessary or appropriate in the public interest or for the protection of investors and municipal entities or obligated persons.[7] A professional qualification examination is intended to determine whether an individual meets the MSRB's basic qualification standards for a particular registration category. The examination measures a candidate's knowledge of the business activities, as well as the regulatory requirements, including MSRB rules, SEC rules, rule interpretations and other federal law, applicable to a particular registration category.

MSRB Rule G–3(d) defines a municipal advisor representative as a natural person associated with a municipal advisor who engages in municipal advisory activities on the municipal advisor's behalf, other than a person performing only clerical, administrative, support or similar functions. Pursuant to MSRB Rule G–3(d), every Municipal Advisor Representative is required to pass the Municipal Advisor Representative Qualification Examination prior to acting in such capacity.

The Series 50 examination will consist of 100 multiple-choice questions. Candidates are allowed 180 minutes to complete the examination.[8] Consistent with other financial regulatory qualification examinations, candidates may receive (at the option of their firm) an informational breakdown of their performance on each section of the examination and their pass/fail status at the completion of the testing session. The passing score for the Series 50 examination is 71%.

Current Content Outline

The Series 50 examination content outline has been prepared to assist municipal advisor representative candidates in preparing for the Series 50 examination and is available on the MSRB's Web site. The Series 50 examination content outline describes the following five topical sections comprising the examination:

(1) Understanding SEC and MSRB Rules Regarding Municipal Advisors (12 questions);

(2) Understanding Municipal Finance (35 questions);

(3) Performing Issuer's Credit Analysis and Due Diligence (12 questions);

(4) Structuring, Pricing and Executing Municipal Debt Products (31 questions); and

(5) Understanding Requirements Related to the Issuance of Municipal Debt (10 questions).

The reference materials section of the Series 50 examination content outline is intended to provide candidates with a list of resources, which when used in conjunction with the Series 50 examination content outline, can assist candidates in preparing for the Series 50 examination. The reference materials were recommended by municipal advisors as having been helpful resources in carrying out the job functions of a municipal advisor. The reference materials are not intended to be all-inclusive, nor are the reference materials intended to specifically represent content that may be covered on the examination.

Proposed Revisions

As a result of recent changes to MSRB rules, revisions to the Series 50 content outline are necessary to indicate the current rule requirements and rule citations. A summary of the changes to the content outline for the Series 50 examination, detailed by major topic headings, is provided below:

Introduction

- The passing score of 71% as approved by the Board was added to the introduction section of the outline.

Function 1: Understanding SEC and MSRB Rules Regarding Municipal Advisors

1.1.3 MSRB Rules Governing Activities of Municipal Advisors (*e.g.,* Professional Qualification; Fiduciary Duty; Recordkeeping)

- The rule reference to "MSRB Rule G–32 Disclosure in Connection with Primary Offerings" is being removed from the outline.
- The rule reference to "MSRB Rule G–20 Gifts, Gratuities, Non-Cash Compensation and Expenses of Issuance" is being added to the content outline to reflect the applicability of Rule G–20 to municipal advisors.
- The rule reference to "MSRB Rule G–37 Political Contributions and Prohibitions on Municipal Securities Business and Municipal Advisory Business" is being added to the content outline to reflect the applicability of Rule G–37 to municipal advisors.
- The rule reference to "MSRB Rule G–42 Duties of Non-Solicitor Municipal Advisors" is being added to the content outline to reflect the applicability of Rule G–42 to municipal advisors.

Function 2: Understanding Municipal Finance

2.1.5 Rating Agencies

- The reference to "(major (three)" rating agencies is being removed from the content outline.

Sample Questions

- Sample questions 2, 3, and 4 were replaced with updated sample questions.

2. Statutory Basis

Section 15B(b)(2)(A) of the Act authorizes the MSRB to prescribe standards of training, experience, competence, and such other qualifications for associated persons of municipal advisors as the Board finds necessary or appropriate in the public interest or for the protection of investors and municipal entities or obligated persons.[9] Section 15B(b)(2)(A)(i)–(iii) of the Act also provides that the Board may appropriately classify municipal advisors and persons associated with municipal advisors and require persons in any such class to pass tests prescribed by the Board.[10]

The MSRB believes that the proposed rule change is consistent with the provisions of Section 15(B)(b)(2)(A) of the Act[11] in that the revisions will ensure that certain key concepts and rules are tested on the Series 50 examination in order to test the competency of individuals seeking to qualify as Municipal Advisor Representatives with respect to their knowledge of MSRB rules and the municipal securities market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The MSRB does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The updated Series 50 examination content outline aligns with the functions and associated tasks currently performed by Municipal Advisor Representatives and tests knowledge of the most current laws, rules, and regulations and skills relevant to those functions and associated tasks. As such, the proposed rule change would make the Series 50 examination more efficient and effective.

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[6] 15 U.S.C. 78*o*–4(b)(2)(L)(iii).

[7] *See* Section 15B(b)(2)(A)(iii) of the Act, 15 U.S.C. 78*o*–4(b)(2)(A)(iii).

[8] Prior to beginning the examination, candidates will receive a tutorial on how to complete the computerized examination. Candidates will be given 30 minutes to complete the tutorial in addition to the 180 minutes allowed to complete the examination.

[9] 15 U.S.C. 78*o*–4(b)(2)(A).

[10] 15 U.S.C. 78*o*–4(b)(2)(A)(i)–(iii).

[11] 15 U.S.C. 78*o*–4(b)(2)(A).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and paragraph (f)(1) of Rule 19b–4 thereunder.[13] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MSRB–2016–08 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2016–08. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MSRB–2016–08 and should be submitted on or before July 26, 2016.

For the Commission, pursuant to delegated authority.[14]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–15759 Filed 7–1–16; 8:45 am]

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[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(1).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78178; File No. SR–BYX–2012–019]

Self-Regulatory Organization; BATS BYX-Exchange, Inc.; Order Granting an Extension to Limited Exemption From Rule 612(c) of Regulation NMS in Connection With the Exchange's Retail Price Improvement Program

June 28, 2016.

On November 27, 2012, the Securities and Exchange Commission ("Commission") issued an order pursuant to its authority under Rule 612(c) of Regulation NMS ("Sub-Penny Rule")[1] that granted the BATS BYX-Exchange, Inc. ("BYX" or the "Exchange") a limited exemption from the Sub-Penny Rule in connection with the operation of the Exchange's Retail Price Improvement ("RPI") Program (the "Program"). The limited exemption was granted concurrently with the Commission's approval of the Exchange's proposal to adopt the Program for a one-year pilot term.[2] The exemption was granted coterminous with the effectiveness of the pilot Program and has been extended three times;[3] both the pilot Program and exemption are scheduled to expire on July 31, 2016.

The Exchange now seeks to extend the exemption until July 31, 2017.[4] The Exchange's request was made in conjunction with an immediately effective filing that extends the operation of the Program until July 31, 2017.[5] In its request to extend the exemption, the Exchange notes that the Program was implemented gradually over time. Accordingly, the Exchange has asked for additional time to allow itself and the Commission to analyze data concerning the Program, which the Exchange committed to provide to the Commission, as well as to allow additional opportunities for greater participation in the Program.[6] For this reason and the reasons stated in the Order originally granting the limited exemption, the Commission finds that extending the exemption, pursuant to its authority under Rule 612(c) of Regulation NMS, is appropriate in the public interest and consistent with the protection of investors.

THEREFORE, IT IS HEREBY ORDERED, that, pursuant to Rule 612(c) of Regulation NMS, the Exchange is granted a limited exemption from Rule 612(c) of Regulation NMS that allows it to accept and rank orders priced equal to or greater than $1.00 per share in increments of $0.001, in connection with the operation of its RPI Program.

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[1] 17 CFR 242.612(c).

[2] *See* Securities Exchange Act Release No. 68303 (November 27, 2012), 77 FR 71652 (December 3, 2012) ("RPI Approval Order") (SR–BXY–2012–019).

[3] *See* Securities Exchange Act Release Nos. 71249 (January 7, 2014), 79 FR 2229 (January 13, 2012) (SR–BYX–2014–001) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Pilot Period for the RPI); 71250 (January 7, 2014), 79 FR 2234 (January 13, 2012) (Order Granting an Extension to Limited Exemption From Rule 612(c) of Regulation NMS in Connection With the Exchange's Retail Price Improvement Program); 74111 (January 22, 2015), 80 FR 4598 (January 28, 2015) (SR–BYX–2015–05) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Pilot Period for the RPI); and 74115 (January 22, 2015), 80 FR 4324 (January 27, 2015) (Order Granting an Extension to Limited Exemption From Rule 612(c) of Regulation NMS in Connection With the Exchange's Retail Price Improvement Program); 76965 (January 22, 2016), 81 FR 4682 (January 27, 2016) (SR–BYX–2016–01) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Extend the Pilot Period for the RPI); 76953 (January 21, 2016), 81 FR 4728 (January 27, 2016) (Order Granting an Extension to Limited Exemption From Rule 612(c) of Regulation NMS in Connection With the Exchange's Retail Price Improvement Program).

[4] *See* letter from Anders Franzon, Senior Vice President and Associate General Counsel, BYX, to Brent J. Fields, Secretary, Commission, dated June 23, 2016.

[5] *See* SR-BatsBYX–2016–15.

[6] *See* RPI Approval Order, *supra* note 2, at 77 FR at 71657.

The limited and temporary exemption extended by this Order is subject to modification or revocation if at any time the Commission determines that such action is necessary or appropriate in furtherance of the purposes of the Securities Exchange Act of 1934. Responsibility for compliance with any applicable provisions of the federal securities laws must rest with the persons relying on the exemptions that are the subject of this Order.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–15756 Filed 7–1–16; 8:45 am]

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[7] 17 CFR 200.30–3(a)(83).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78182; File No. SR–FINRA–2016–020]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Implementation of FINRA Rule 4240 (Margin Requirements for Credit Default Swaps)

June 28, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 15, 2016, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to extend to July 18, 2017 the implementation of FINRA Rule 4240. FINRA Rule 4240 implements an interim pilot program with respect to margin requirements for certain transactions in credit default swaps that are security-based swaps.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org*, at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On May 22, 2009, the Commission approved FINRA Rule 4240,[4] which implements an interim pilot program (the ''Interim Pilot Program'') with respect to margin requirements for certain transactions in credit default swaps (''CDS'').[5] On May 20, 2015, FINRA filed a proposed rule change for immediate effectiveness extending the implementation of FINRA Rule 4240 to July 18, 2016.[6]

As explained in the Approval Order, FINRA Rule 4240, coterminous with certain Commission actions, was intended to address concerns arising from systemic risk posed by CDS, including, among other things, risks to the financial system arising from the lack of a central clearing counterparty to clear and settle CDS.[7] On July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act''),[8] Title VII of which established a comprehensive new regulatory framework for swaps and security-based swaps,[9] including certain CDS. The new legislation was intended, among other things, to enhance the authority of regulators to implement new rules designed to reduce risk, increase transparency, and promote market integrity with respect to such products.

Pursuant to Title VII of the Dodd-Frank Act, the CFTC and the Commission are engaged in ongoing rulemaking with respect to swaps and security-based swaps.[10] The Commission has, among other things, proposed rules with respect to capital, margin and segregation requirements for security-based swap dealers and major security-based swap participants and capital requirements for broker-dealers.[11] FINRA believes it is appropriate to extend the Interim Pilot Program for a limited period, to July 18, 2017, in light of the continuing development of the CDS business within the framework of the Dodd-Frank Act and pending the final implementation of new CFTC and SEC rules pursuant to Title VII of that legislation. FINRA is considering proposing additional amendments to the Interim Pilot Program.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] *See* Securities Exchange Act Release No. 59955 (May 22, 2009), 74 FR 25586 (May 28, 2009) (Order Approving File No. SR–FINRA–2009–012) (''Approval Order'').

[5] In March 2012, the SEC approved amendments to FINRA Rule 4240 that, among other things, limit at this time the rule's application to credit default swaps that are security-based swaps. *See* Securities Exchange Act Release No. 66527 (March 7, 2012), 77 FR 14850 (March 13, 2012) (Order Approving File No. SR–FINRA–2012–015).

[6] *See* Securities Exchange Act Release No. 75069 (May 29, 2015), 80 FR 31931 (June 4, 2015) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2015–013).

[7] *See* Approval Order, 74 FR at 25588–89.

[8] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (2010).

[9] The terms ''swap'' and ''security-based swap'' are defined in Sections 721 and 761 of the Dodd-Frank Act. The Commodity Futures Trading Commission (''CFTC'') and the Commission jointly have approved rules to further define these terms. *See* Securities Exchange Act Release No. 67453 (July 18, 2012), 77 FR 48208 (August 13, 2012) (Joint Final Rule; Interpretations; Request for Comment on an Interpretation: Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping). *See also* Securities Exchange Act Release No. 66868 (April 27, 2012), 77 FR 30596 (May 23, 2012) (Joint Final Rule; Joint Interim Final Rule; Interpretations: Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant'' and ''Eligible Contract Participant'').

[10] *See, e.g.,* Securities Exchange Act Release No. 67177 (June 11, 2012), 77 FR 35625 (June 14, 2012) (Notice of Statement of General Policy with Request for Public Comment: Statement of General Policy on the Sequencing of the Compliance Dates for Final Rules Applicable to Security-Based Swaps Adopted Pursuant to the Securities Exchange Act of 1934 and the Dodd-Frank Wall Street Reform and Consumer Protection Act).

[11] *See* Securities Exchange Act Release No. 68071 (October 18, 2012), 77 FR 70214 (November 23, 2012) (Proposed Rule: Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital Requirements for Broker-Dealers). *See also* Securities Exchange Act Release No. 71958 (April 17, 2014), 79 FR 25194 (May 2, 2014) (Proposed Rule: Recordkeeping and Reporting Requirements for Security-Based Swap Dealers, Major Security-Based Swap Participants, and Broker-Dealers; Capital Rule for Certain Security-Based Swap Dealers).

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is proposing that the implementation date of the proposed rule change will be July 18, 2016. The proposed rule change will expire on July 18, 2017.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[12] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change is consistent with the Act because, in light of the continuing development of the CDS business within the framework of the Dodd-Frank Act and pending the final implementation of new CFTC and SEC rules pursuant to Title VII of that legislation, extending the implementation of the margin requirements as set forth by FINRA Rule 4240 will help to stabilize the financial markets.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that extending the implementation of FINRA Rule 4240 for a limited period, to July 18, 2017, in light of the continuing development of the CDS business within the framework of the Dodd-Frank Act and pending the final implementation of new CFTC and SEC rules pursuant to Title VII of that legislation, helps to promote stability in the financial markets and regulatory certainty for members.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2016–020 on the subject line.

Paper Comments

- Send paper comments in triplicate to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2016–020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2016–020 and should be submitted on or before July 26, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–15758 Filed 7–1–16; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2016–0030]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections and one new collection.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA,

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[12] 15 U.S.C. 78*o*–3(b)(6).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 200.30–3(a)(12).

Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov,*
(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2016–0030].

I. The information collection below is pending at SSA. SSA will submit it to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than September 6, 2016. Individuals can obtain copies of the collection instrument by writing to the above email address.

Request to Withdraw a Hearing Request; Request to Withdraw an Appeals Council Request for Review; and Administrative Review Process for Adjudicating Initial Disability Claims—20 CFR parts 404, 405, and 416—0960–0710. Claimants have a statutory right under the Social Security Act (Act) and current regulations to apply for Disability (SSDI) benefits or Supplemental Security Income (SSI) payments. SSA collects information at each step of the administrative process to adjudicate claims fairly and efficiently. SSA collects this information to establish a claimant's right to administrative review and determine the severity of the claimant's alleged impairments. SSA uses the information we collect to determine entitlement or continuing eligibility to SSDI benefits or SSI payments, and to enable appeals of these determinations. In addition, SSA collects information on Forms HA–85 and HA–86 to allow claimants to withdraw a hearing request or an Appeals Council review request. The respondents are applicants for Title II SSDI or Title XVI SSI benefits; their appointed representatives; legal advocates; medical sources; and schools.

Type of Request: Revision of an OMB-approved information collection.

20 CFR section No.	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
404.961, 416.1461, 405.330, and 405.366	12,220	1	20	4,073
404.950, 416.1450, and 405.332	1,040	1	20	347
404.949 and 416.1449	2,868	1	60	2,868
405.334	20	1	60	20
404.957, 416.1457, and 405.380	21,041	1	10	3,507
405.381	37	1	30	19
405.401	5,310	1	10	885
404.971 and 416.1471 (HA–85; HA-86)	1,606	1	10	268
404.982 and 416.1482	1,687	1	30	844
404.987 & 404.988 and 416.1487 & 416.1488 and 405.601	12,425	1	30	6,213
405.372(c)	5,310	1	10	885
405.1(b)(5), 405.372(b)	833	1	30	417
405.505	833	1	30	417
405.1(c)(2)	5,310	1	10	885
405.20	5,310	1	10	885
Totals	75,850	....	....	22,533

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding the information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than August 4, 2016. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. Report of Adult Functioning-Employer—20 CFR 404.1512 and 20 CFR 416.912—0960—NEW. Section 205(a), 223(d)(5)(A), 1631(d)(1), and 1631(e)(1) of the Act require claimants' applying for SSDI benefits or SSI payments to provide SSA with medical and other evidence of their disability. 20 CFR 404.1512 and 20 CFR 416.912 of the Code of Federal Regulations provides detailed requirements of the types of evidence SSDI beneficiaries and SSI claimants must provide showing how their impairment(s) affects their ability to work (*e.g.,* evidence of age, education and training, work experience, daily activities, efforts to work, and any other evidence). Past employers familiar with the claimant's ability to perform work activities completes Form SSA–3385–BK, Report of Adult Functioning-Employer to provide SSA with information about the employees day-to-day functioning in the work setting. SSA and Disability Determination Services use the information Form SSA–3385–BK collects as the basis to determine eligibility or continued eligibility for disability benefits. The respondents are claimants' past employers.

Type of Request: This is a new information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–3385–BK	3,900	1	20	1,300

2. Report to United States Social Security Administration by Person Receiving Benefits for a Child or for an Adult Unable to Handle Funds; Report to the United States Social Security Administration—0960–0049. Section 203(c) of the Act requires the Commissioner of SSA to make benefit deductions from the following

categories: (1) Entitled individuals who engage in remunerative activity outside of the United States in excess of 45 hours a month; and (2) beneficiaries who fail to have in their care the specified entitled child beneficiaries. SSA uses Forms SSA–7161–OCR–SM and SSA–7162–OCR–SM to: (1) Determine continuing entitlement to Social Security benefits; (2) correct benefit amounts for beneficiaries outside the United States; and (3) monitor the performance of representative payees outside the United States. This collection is mandatory as an annual (or every other year, depending on the country of residence) review for fraud prevention. In addition, the results can affect benefits by increasing or decreasing payment amount or by causing SSA to suspend or terminate benefits. The respondents are individuals living outside the United States who are receiving benefits on their own (or on behalf of someone else) under Title II of the Act.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–7161–OCR–SM	42,176	1	15	10,544
SSA–7162–OCR–SM	394,419	1	5	32,868
Totals	436,595			43,412

Dated: June 28, 2016.

Naomi R. Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2016–15763 Filed 7–1–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 9625]

Executive Order 13224 Designation of Asim Umar, aka Asim Umer, aka Maulana Asim Umar, aka Sanaul Haq, as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the entity known as Asim Umar, aka Asim Umer, aka Maulana Asim Umar, aka Sanaul Haq, poses a significant risk of committing acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: June 24, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2016–15829 Filed 7–1–16; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice 9627]

30-Day Notice of Proposed Information Collection: Statement of Consent: Issuance of a U.S. Passport to a Minor Under Age 16

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to August 4, 2016.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, by mail to PPT Forms Officer, U.S. Department of State, CA/PPT/S/L/LA 44132 Mercure Cir, P.O. Box 1227 Sterling, VA 20166–1227, by phone at (202) 485–6373, or by email at *PPTFormsOfficer@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Statement of Consent: Issuance of a U.S. Passport to a Minor Under Age 16.
- *OMB Control Number:* 1405–0129.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Passport Services, Office of Legal Affairs and Law Enforcement Liaison (CA/PPT/S/L/LA).
- *Form Number:* DS–3053.
- *Respondents:* Individuals.
- *Estimated Number of Respondents:* 465,848.
- *Estimated Number of Responses:* 465,848.
- *Average Time per Response:* 20 min.
- *Total Estimated Burden Time:* 155,127 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required To Obtain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The information collected on the DS–3053 is used to facilitate the issuance of passports to U.S. citizens and nationals under the age of 16. The primary purpose of soliciting the information is to ensure that both parents and/or all guardians consent to the issuance of a passport to a minor under age 16, unless the applying parent has sole custody or there are exigent or special family circumstances.

Methodology

Passport Services collects information from parents or legal guardians of U.S. citizens and non-citizen nationals' minors when they complete and submit the Statement of Consent or Special Circumstances: Issuance of a Passport to a Minor under Age 16. Passport applicants can either download the DS–3053 from the internet or obtain one from an Acceptance Facility/Passport Agency. The form must be completed, signed, and submitted along with the applicant's DS–11, Application for a U.S. Passport.

Dated: June 28, 2016.

Brenda S. Sprague,

Deputy Assistant Secretary for Passport Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 2016–15826 Filed 7–1–16; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice 9623]

Imposition of Nonproliferation Measures Against Foreign Persons, Including a Ban on U.S. Government Procurement

AGENCY: Bureau of International Security and Nonproliferation, Department of State.

ACTION: Notice.

SUMMARY: A determination has been made that a number of foreign persons have engaged in activities that warrant the imposition of measures pursuant to Section 3 of the Iran, North Korea, and Syria Nonproliferation Act. The Act provides for penalties on foreign entities and individuals for the transfer to or acquisition from Iran since January 1, 1999; the transfer to or acquisition from Syria since January 1, 2005; or the transfer to or acquisition from North Korea since January 1, 2006, of goods, services, or technology controlled under multilateral control lists (Missile Technology Control Regime, Australia Group, Chemical Weapons Convention, Nuclear Suppliers Group, Wassenaar Arrangement) or otherwise having the potential to make a material contribution to the development of weapons of mass destruction (WMD) or cruise or ballistic missile systems. The latter category includes (a) items of the same kind as those on multilateral lists but falling below the control list parameters when it is determined that such items have the potential of making a material contribution to WMD or cruise or ballistic missile systems, (b) items on U.S. national control lists for WMD/missile reasons that are not on multilateral lists, and (c) other items with the potential of making such a material contribution when added through case-by-case decisions.

DATES: Effective Date: June 28, 2016.

FOR FURTHER INFORMATION CONTACT: On general issues: Pam Durham, Office of Missile, Biological, and Chemical Nonproliferation, Bureau of International Security and Nonproliferation, Department of State, Telephone (202) 647–4930. For U.S. Government procurement ban issues: Eric Moore, Office of the Procurement Executive, Department of State, Telephone: (703) 875–4079.

SUPPLEMENTARY INFORMATION: On June 22, 2016 the U.S. Government determined that the measures authorized in Section 3 of the Iran, North Korea, and Syria Nonproliferation Act (Pub. L. 109–353) shall apply to the following foreign persons identified in the report submitted pursuant to Section 2(a) of the Act:

Belvneshpromservice (BVPS) (Belarus) and any successor, sub-unit, or subsidiary thereof;
Composite International (China) and any successor, sub-unit, or subsidiary thereof;
Cosailing Business Trading Company (China) and any successor, sub-unit, or subsidiary thereof;
Do Best Industry Co., Ltd (China) and any successor, sub-unit, or subsidiary thereof;
Global Holding Group Company (China) and any successor, sub-unit, or subsidiary thereof;
Jack Qin (China);
Li Fangwei (aka Karl Lee) (China);
Ningbo Jiahe Trading Co., Ltd (China) and any successor, sub-unit, or subsidiary thereof;
Ningbo New Century (China) and any successor, sub-unit, or subsidiary thereof;
Richard Yue (China);
Sinotech (Dalian) Carbon and Graphite Corporation (SCGC) (China) and any successor, sub-unit, or subsidiary thereof;
Shanghai Electric International Economic & Trading Company (SEIC) (China) and any successor, sub-unit, or subsidiary thereof:
Xi'an Jiate Titanium Industry Company (China) and any successor, sub-unit, or subsidiary thereof;
Asaib ahl Haq (AAH) (Iraq) and any successor, sub-unit, or subsidiary thereof;
Khata'ib Hezbollah (KH) (Iraq) and any successor, sub-unit, or subsidiary thereof;
Islamic Revolutionary Guard Corps Qods Force (IRGC QF) (Iran) and any successor, sub-unit, or subsidiary thereof;
Shahid Moghadam-Yazd Marine Industries (SMYM) (Iran) and any successor, sub-unit, or subsidiary thereof;
Shiraz Electronic Industries (SEI) Company (Iran) and any successor, sub-unit, or subsidiary thereof;
Budaya Kita Sdn Bhd (BK) (Malaysia) and any successor, sub-unit, or subsidiary thereof;
Mohammad Rafie Ab Malek (Malaysia);
Kay Marine Sdn. Bhd. (Malaysia) and any successor, sub-unit, or subsidiary thereof;
Kang Mun-kil (North Korea);
Korea Namhung Trading Corporation (North Korean entity operating in China) and any successor, sub-unit, or subsidiary thereof;
Saeng Pil Trading Corporation (STC) (North Korea) and any successor, sub-unit, or subsidiary thereof;
General Department of Military Cooperation (North Korea) and any successor, sub-unit, or subsidiary thereof;
150th Aircraft Repair Plant (ARZ) (Kaliningrad) (Russia) and any successor, sub-unit, or subsidiary thereof;
Instrument Building Design Bureau (KBP) Tula (Russia) and any successor, sub-unit, or subsidiary thereof;
Kolomna Design Bureau of Machine-Building (KBM) (Russia) and any

successor, sub-unit, or subsidiary thereof;
Kuntsevo Design Bureau (Russia) and any successor, sub-unit, or subsidiary thereof;
NPO Mashinostroyeniya (NPOM) (Russia) and any successor, sub-unit, or subsidiary thereof;
Military Industrial Corporation (MIC) (Sudan) and any successor, sub-unit, or subsidiary thereof;
Khartoum Industrial Complex (Giad) (Sudan) and any successor, sub-unit, or subsidiary thereof;
Khartoum Military Industrial Complex (Yarmouk) (Sudan) and any successor, sub-unit, or subsidiary thereof;
Vega Aeronautics and Engineering Company Ltd (Sudan) and any successor, sub-unit, or subsidiary thereof;
Scientific Studies and Research Center (SSRC) (Syria) and any successor, sub-unit, or subsidiary thereof;
Lebanese Hizballah (Syria) and any successor, sub-unit, or subsidiary thereof; and
Luwero Industries Ltd (Uganda) and any successor, sub-unit, or subsidiary thereof.

Accordingly, pursuant to Section 3 of the Act, the following measures are imposed on these persons:

1. No department or agency of the United States Government may procure or enter into any contract for the procurement of any goods, technology, or services from these foreign persons, except to the extent that the Secretary of State otherwise may determine;

2. No department or agency of the United States Government may provide any assistance to these foreign persons, and these persons shall not be eligible to participate in any assistance program of the United States Government, except to the extent that the Secretary of State otherwise may determine;

3. No United States Government sales to these foreign persons of any item on the United States Munitions List are permitted, and all sales to these persons of any defense articles, defense services, or design and construction services under the Arms Export Control Act are terminated; and

4. No new individual licenses shall be granted for the transfer to these foreign persons of items the export of which is controlled under the Export Administration Act of 1979 or the Export Administration Regulations, and any existing such licenses are suspended.

These measures shall be implemented by the responsible departments and agencies of the United States Government and will remain in place for two years from the effective date, except to the extent that the Secretary of State may subsequently determine otherwise.

Dated: June 27, 2016.

Vann H. Van Diepen,

Acting Assistant Secretary of State for International Security and Nonproliferation.

[FR Doc. 2016–15828 Filed 7–1–16; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF STATE

[Public Notice: 9622]

Exchange Visitor Program—Use of Forms DS–2019 in the Summer Work Travel Program

AGENCY: Department of State.

ACTION: Re-allocation of Forms DS–2019 to designated Summer Work Travel Sponsors.

SUMMARY: The Department of State (the Department) will permit current sponsors in the Summer Work Travel (SWT) program category to apply to the Department for a program adjustment by allocation of Forms DS–2019 that were previously allocated to SWT sponsors in business for the full 2011 calendar year, but which no longer operate in the SWT program category. These forms are not currently allocated to any sponsor. If allocated, the total number of SWT program participants would remain within the aggregate actual total SWT participant program size for 2011 (*i.e.*, the overall program participant level and designation moratorium established by the notice published by the Department in 2011 (Public Notice 7677, 76 FR 68808).

DATES: Effective September 1, 2016.

FOR FURTHER INFORMATION CONTACT: G. Kevin Saba, Director, Office of Policy and Program Support, Bureau of Educational and Cultural Affairs, U.S. Department of State, SA–5, Floor 5, 2200 C Street NW., Washington, DC 20522; or email at *JExchanges@state.gov.*

SUPPLEMENTARY INFORMATION: The Department administers the Exchange Visitor Program pursuant to the Mutual Educational and Cultural Exchange Act of 1961, as amended (22 U.S.C. 2451 *et. seq.*), also known as the Fulbright-Hays Act (the Act). The purpose of the Act is to increase mutual understanding between the people of the United States and the people of other countries, including through educational and cultural exchanges. The Department's implementing regulations for the Exchange Visitor Program are set forth at 22 CFR part 62.

On November 7, 2011, the Office of Private Sector Exchange published Public Notice 7677, which provided that, until further notice, SWT program sponsors in business for the full 2011 calendar year would not be permitted to expand their number of program participants beyond their actual total 2011 participant program size (a cap), and that no new applications from prospective sponsors for SWT program designation would be accepted (a moratorium).

In effect, the cap limited the SWT program's aggregate size to the 2011 participant level, which was 109,187 participants, and the moratorium fixed the 50 designated sponsors active in the 2011 SWT program. The purpose of the cap and moratorium was to give the Department time to review and take next steps in reforming the SWT program.

Since 2011, the Department has implemented significant reforms of the SWT program, reflected in several rulemakings, increases in Department staff to monitor SWT program implementation in the field, compliance reviews, and periodic Department-sponsor dialogue sessions.

Between 2011 and 2015, the number of designated SWT program sponsors operating in the SWT program decreased from 50 to 41. In 2015, 12,959 fewer exchange visitors could participate in the SWT program than the 109,187 participants that constituted the aggregate actual total program participant size in 2011.

This notice informs SWT program sponsors that they may apply to adjust their number of program participants beyond their respective, sponsor-specific 2011 participant program size. A designated sponsor in good standing (one without imposed sanctions in the SWT program category), and currently active in the SWT program, may apply in writing to the Department's Office of Designation, on or after September 1, 2016, for program adjustment pursuant to 22 CFR 62.12(d).

22 CFR 62.12(d)(2) provides that a request for program adjustment must include certain required information as well as any other information requested by the Department. The Department requests that, pursuant to § 62.12(d)(2), an application for SWT program adjustment include information about the sponsor's:

(1) Ability to meet emerging foreign policy priorities through increased people-to-people exchanges;

(2) need to meet demand while maintaining an equitable balance between summer (northern hemisphere)

and winter (southern hemisphere) cycles of the SWT program; or

(3) ability to address exigent diplomatic needs that can be served by increased people-to-people exchanges.

The Department has the sole discretion to determine the number of Forms DS–2019 to be issued to a sponsor. *See* 22 CFR 62.12(d)(1). The overall number of program participants in the SWT program remains limited by the SWT program's aggregate size at the 2011 participant level established by Public Notice 7677. No new applications from prospective sponsors for SWT program designation will be accepted at this time.

Dated: June 27, 2016.

G. Kevin Saba,

Director, Office of Policy and Program Support, Bureau of Educational and Cultural Affairs.

[FR Doc. 2016–15831 Filed 7–1–16; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 9624]

Imposition of Nonproliferation Measures Against Foreign Person, Including a Ban on U.S. Government Procurement

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: A determination has been made that a foreign person has engaged in activities that warrant the imposition of measures pursuant to Section 3 of the Iran, North Korea, and Syria Nonproliferation Act. The Act provides for penalties on foreign entities and individuals for the transfer to or acquisition from Iran since January 1, 1999; the transfer to or acquisition from Syria since January 1, 2005; or the transfer to or acquisition from North Korea since January 1, 2006, of goods, services, or technology controlled under multilateral control lists (Missile Technology Control Regime, Australia Group, Chemical Weapons Convention, Nuclear Suppliers Group, Wassenaar Arrangement) or otherwise having the potential to make a material contribution to the development of weapons of mass destruction (WMD) or cruise or ballistic missile systems. The latter category includes (a) items of the same kind as those on multilateral lists but falling below the control list parameters when it is determined that such items have the potential of making a material contribution to WMD or cruise or ballistic missile systems, (b) items on U.S. national control lists for WMD/missile reasons that are not on multilateral lists, and (c) other items with the potential of making such a material contribution when added through case-by-case decisions.

DATES: *Effective Date:* June 28, 2016.

FOR FURTHER INFORMATION CONTACT: On general issues: Pam Durham, Office of Missile, Biological, and Chemical Nonproliferation, Bureau of International Security and Nonproliferation, Department of State, Telephone (202) 647–4930. For U.S. Government procurement ban issues: Eric Moore, Office of the Procurement Executive, Department of State, Telephone: (703) 875–4079.

SUPPLEMENTARY INFORMATION: On June 22, 2016 the U.S. Government determined that the measures authorized in Section 3 of the Iran, North Korea, and Syria Nonproliferation Act (Pub. L. 109–353) shall apply to the following foreign person identified in the report submitted pursuant to Section 2(a) of the Act:

Rosoboronexport (ROE) (Russia) and any successor, sub-unit, or subsidiary thereof.

Accordingly, pursuant to Section 3 of the Act, the following measures are imposed on these persons:

1. No department or agency of the United States Government may procure or enter into any contract for the procurement of any goods, technology, or services from these foreign persons, except to the extent that the Secretary of State otherwise may determine. This measure shall not apply to subcontracts at any tier with ROE and any successor, sub-unit, or subsidiary thereof made on behalf of the United States Government for goods, technology, and services for the maintenance, repair, overhaul, or sustainment of Mi-17 helicopters for the purpose of providing assistance to the security forces of Afghanistan, as well as for the purpose of combating terrorism and violent extremism globally. Such subcontracts include the purchase of spare parts, supplies, and related services for these purposes;

2. No department or agency of the United States Government may provide any assistance to these foreign persons, and these persons shall not be eligible to participate in any assistance program of the United States Government, except to the extent that the Secretary of State otherwise may determine;

3. No United States Government sales to these foreign persons of any item on the United States Munitions List are permitted, and all sales to these persons of any defense articles, defense services, or design and construction services under the Arms Export Control Act are terminated; and

4. No new individual licenses shall be granted for the transfer to these foreign persons of items the export of which is controlled under the Export Administration Act of 1979 or the Export Administration Regulations, and any existing such licenses are suspended.

These measures shall be implemented by the responsible departments and agencies of the United States Government and will remain in place for two years from the effective date, except to the extent that the Secretary of State may subsequently determine otherwise.

Dated: June 27, 2016.

Vann H. Van Diepen,

Acting Assistant Secretary of State for International Security and Nonproliferation.

[FR Doc. 2016–15832 Filed 7–1–16; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF STATE

[Public Notice 9626]

30-Day Notice of Proposed Information Collection: Statement of Exigent/Special Family Circumstances for Issuance of a U.S. Passport to a Minor Under Age 16

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to August 4, 2016.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, by mail to PPT Forms Officer, U.S. Department of State, CA/PPT/S/L/LA, 44132 Mercure Cir, P.O. Box 1227 Sterling, VA 20166–1227, by phone at (202) 485–6373, or by email at *PPTFormsOfficer@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Statement of Exigent/Special Family Circumstances for Issuance of a U.S. Passport to a Minor Under Age 16.
- *OMB Control Number:* 1405–0216.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Passport Services, Office of Legal Affairs and Law Enforcement Liaison (CA/PPT/S/L/LA).
- *Form Number:* DS–5525.
- *Respondents:* Individuals.
- *Estimated Number of Respondents:* 43,526.
- *Estimated Number of Responses:* 43,526.
- *Average Time per Response:* 30 min.
- *Total Estimated Burden Time:* 21,763 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required To Obtain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection:

The information collected on the DS–5525, "Statement of Exigent/Special Family Circumstances for Issuance of a U.S. Passport to a Minor under Age 16", is used in conjunction with the DS–11, "Application for a U.S. Passport". The DS–5525 can serve as the statement describing exigent or special family circumstances, which is required if written consent of the non-applying parent or guardian cannot be obtained when a passport application is executed for a minor under age 16.

Methodology:

Passport Services collects information from U.S. citizens and non-citizen U.S. nationals when they complete and submit the DS–5525, "Statement of Exigent/Special Family Circumstances for Issuance of a U.S. Passport to a Minor under Age 16". Passport applicants can either download the DS–5525 from the internet or obtain the form from an Acceptance Facility/Passport Agency. The form must be completed, signed, and submitted along with the applicant's DS–11, "Application for a U.S. Passport".

Dated: June 28, 2016.

Brenda S. Sprague,

Deputy Assistant Secretary for Passport Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 2016–15827 Filed 7–1–16; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Membership in the National Parks Overflights Advisory Group Aviation Rulemaking Committee

AGENCY: Federal Aviation Administration, Transportation.

ACTION: Notice.

SUMMARY: By **Federal Register** notice (See 81 FR 24686–24687, April 26, 2016) the National Park Service (NPS) and the Federal Aviation Administration (FAA) invited interested persons to apply to fill one current vacancy on the National Parks Overflights Advisory Group (NPOAG) Aviation Rulemaking Committee (ARC). The notice invited interested persons to apply to fill the opening to represent environmental concerns. This notice informs the public of the person selected to fill that current opening.

FOR FURTHER INFORMATION CONTACT: Keith Lusk, Special Programs Staff, Federal Aviation Administration, Western-Pacific Region Headquarters, P.O. Box 92007, Los Angeles, CA 90009–2007, telephone: (310) 725–3808, email: *Keith.Lusk@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Parks Air Tour Management Act of 2000 (the Act) was enacted on April 5, 2000, as Public Law 106–181, and subsequently amended in the FAA Modernization and Reform Act of 2012. The Act required the establishment of the advisory group within 1 year after its enactment. The NPOAG was established in March 2001. The advisory group is comprised of a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairman of the advisory group.

In accordance with the Act, the advisory group provides "advice, information, and recommendations to the Administrator and the Director—

(1) On the implementation of this title [the Act] and the amendments made by this title;

(2) On commonly accepted quiet aircraft technology for use in commercial air tour operations over a national park or tribal lands, which will receive preferential treatment in a given air tour management plan;

(3) On other measures that might be taken to accommodate the interests of visitors to national parks; and

(4) At the request of the Administrator and the Director, safety, environmental, and other issues related to commercial air tour operations over a national park or tribal lands."

Membership

The current NPOAG ARC is made up of one member representing general aviation, three members representing the commercial air tour industry, four members representing environmental concerns, and two members representing Native American interests. Current members of the NPOAG ARC are as follows:

Melissa Rudinger representing general aviation; Alan Stephen, Matt Zuccaro, and Mark Francis representing commercial air tour operators; Mark Belles, Nicholas Miller, and Dick Hingson representing environmental interests with one open seat; and Leigh Kuwanwisiwma and Martin Begaye representing Native American tribes.

Selection

The person selected to fill the current open seat representing environmental concerns is Rob Smith. Mr Smith's 3-year terms will begin on the publication date of this notice.

Issued in Hawthorne, CA on June 27, 2016.

Keith Lusk,

Program Manager, Special Programs Staff, Western-Pacific Region.

[FR Doc. 2016–15762 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Request To Release Airport Property

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on request to release airport property at Waterloo Regional Airport, Waterloo, Iowa. (ALO)

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at Waterloo Regional Airport, Waterloo, Iowa, under the provisions of 49 U.S.C. 47107(h)(2).

DATES: Comments must be received on or before August 4, 2016.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust Room 364, Kansas City, MO 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: Keith Kaspari, Director of Aviation, 2790 Livingston Ln., Waterloo, IA 50703, (319) 291–4483.

FOR FURTHER INFORMATION CONTACT: Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust Room 364, Kansas City, MO 64106, (816) 329–2644, *lynn.martin@faa.gov.*

The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release approximately 0.91± acres of airport property at Waterloo Regional Airport (ALO) under the provisions of 49 U.S.C. 47107(h)(2). On March 29, 2016, the Director of Aviation at Waterloo Regional Airport requested from the FAA that approximately 0.91± acres of property be released for sale to Standard Forwarding for an addition to their trucking business consistent with the zoning ordinances of the City. On June 24, 2016, the FAA determined that the request to release property at Waterloo Regional Airport (ALO) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The following is a brief overview of the request:

The Waterloo Regional Airport (ALO) is proposing the release of airport property totaling 0.91 acres, more or less. This land is to be used for an addition to the Standard Forwarding Company. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at Waterloo Regional Airport (ALO) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in another eligible airport improvement project for general aviation facilities at Waterloo Regional Airport.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**. In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at Waterloo Regional Airport.

Issued in Kansas City, MO on June 24, 2016.

Jim A. Johnson,

Manager, Airports Division.

[FR Doc. 2016–15766 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on the Proposed I–395/Route 9 Transportation Study in Brewer, Holden, Eddington, and Clifton, Maine

AGENCY: Federal Highway Administration (FHWA), U.S. DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and Other Federal Agencies.

SUMMARY: This notice announces actions taken by FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to the proposed I–395/Route 9 Transportation Study Final Environmental Impact Statement (FEIS), located in the City of Brewer, and Towns of Holden, Eddington, and Clifton, Penobscot County, Maine. Those actions grant approvals for the project.

DATES: By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 2, 2016. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Todd D. Jorgensen, Division Administrator, Federal Highway Administration, Edmund S. Muskie Federal Building, 40 Western Avenue, Room 614, Augusta, ME 04330, Telephone (207) 512–4911; or Nathan Howard, Project Manager, Maine Department of Transportation, Child Street, 16 State House Station, Augusta, ME 04333–0016, Telephone (207) 624–3310.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA and other Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the following highway project in the State of Maine: I–395/Route 9 Transportation Study Final Environmental Impact Statement (FEIS), a proposed new controlled access highway extending northeast from the I–395 interchange with Route 1A in Brewer, roughly paralleling the Brewer/Holden town line, and connecting with Route 9 west of Chemo Pond Road in Eddington, Maine. The total length of the proposed I–395/Route 9 connector is approximately 6.1 miles of new construction roadway and also includes about 4.2 miles of existing Route 9. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the FEIS for the project, approved on January 20, 2015, in the FHWA Record of Decision (ROD) issued on June 23, 2016, and in other documents in the FHWA administrative record. The FEIS, ROD, and other documents in the FHWA administrative record file are available by contacting FHWA or the Maine Department of Transportation at the addresses provided above. The FHWA FEIS and ROD can be viewed and downloaded from the project Web site at *http://www.maine.gov/mdot* or viewed at public libraries in the project area. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. Air: Clean Air Act, [42 U.S.C. 7401–7671(q)].

3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Section 6(f) of the Land and Water Conservation Fund Act of 1965 [16 U.S.C. 460]; Farmland Protection Policy Act [7 U.S.C. 4201–4209].

4. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Magnuson-Stevens Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801 *et seq.*]; Bald and Golden Eagle Protection Act of 1940 [16 U.S.C. 668–668c].

5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*].

6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)].

7. Executive Orders; E.O. 11990 Protection of Wetlands; E.O. 11988 Protection of Floodplains; E.O. 12898 Federal Actions to Address Environmental Justice in Minority and Low Income Populations; E.O. 13175 Consultation and Coordination with Indian Tribal Governments.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1), as amended by Moving Ahead for Progress in the 21st Century Act (MAP–21), Pub. L. 112–141, sec. 1308, 126 Stat. 405 (2012).

Issued on: June 23, 2016.

Todd D. Jorgensen,

Division Administrator.

[FR Doc. 2016–15685 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Sunshine Act Meetings; Unified Carrier Registration Plan Board of Directors

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of Unified Carrier Registration Plan Board of Directors Meeting.

TIME AND DATE: The meeting will be held on July 14, 2016, from 12:00 Noon to 3:00 p.m., Eastern Daylight Time.

PLACE: This meeting will be open to the public via conference call. Any interested person may call 1–877–422–1931, passcode 2855443940, to listen and participate in this meeting.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the Board) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement and to that end, may consider matters properly before the Board.

FOR FURTHER INFORMATION CONTACT: Mr. Avelino Gutierrez, Chair, Unified Carrier Registration Board of Directors at (505) 827–4565.

Issued on: June 27, 2016.

Larry W. Minor,

Associate Administrator, Office of Policy, Federal Motor Carrier Safety Administration.

[FR Doc. 2016–15933 Filed 6–30–16; 11:15 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2014–0111]

Hours of Service of Drivers: Application for Renewal of Exemptions From the 14-Hour Rule During Independence Day Celebrations for Illumination Fireworks, LLC and ACE Pyro, LLC

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition; granting of renewal.

SUMMARY: FMCSA announces its decision to grant exemption renewals to Illumination Fireworks, LLC and ACE Pyro, LLC (the applicants) from the prohibition on driving commercial motor vehicles (CMVs) after the 14th hour after coming on duty. The applicants requested the exemption renewals for the period of June 28–July 8, for the next 5 years (2016–2020 inclusive). The applicants were previously granted exemptions during the Independence Day periods of 2014 and 2015. The 5-year renewals will cover the drivers of approximately 50 CMVs employed by the applicants to stage fireworks shows celebrating Independence Day. The Agency has determined that the terms and conditions of the limited exemptions will ensure a level of safety equivalent to, or greater than, the level of safety achieved without the exemptions.

DATES: These exemptions are effective during the periods of June 28 through July 8, 2016 through 2020.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325. Email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, "FMCSA–2014–0111" in the "Keyword" box and click "Search." Next, click "Open Docket Folder" button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305).

The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Application for Exemptions

The hours-of-service (HOS) rule in 49 CFR 395.3(a)(2) prohibits a property-carrying CMV driver from driving a CMV after the 14th hour after coming on duty following 10 consecutive hours off duty. The applicants represent two fireworks display companies that were previously granted exemptions during the Independence Day periods of June 28–July 8, 2014 and 2015. The applicants' initial exemption application for relief from the 14-hour rule, submitted in 2014 and in docket FMCSA–2014–0111, fully describes the CMV operations of fireworks companies during the extended July 4 holiday.

The applicants requested a renewal of their exemptions for the period of June 28–July 8, for the next 5 years (2016–2020 inclusive). Section 5206(a)(2) of the "Fixing America's Surface Transportation Act" (FAST Act) [Pub. L. 114–94, 129 Stat. 1312, Dec. 4, 2015] amended 49 U.S.C. 31315(b) to permit exemptions for no longer than 5 years from their dates of inception.

As stated in the applicants' request, their CMV drivers hold commercial driver's licenses (CDLs) with hazardous materials endorsements and transport Division 1.3G and 1.4G fireworks to set up fireworks shows for Independence Day. The applicants state that compliance with the 14-hour rule would impose economic hardship on cities, municipalities, and themselves because two drivers would be required, significantly increasing the cost of the fireworks display.

The applicants assert that without the extra duty-period provided by the exemption, safety would decline as firework drivers would be unable to return to their home base following each show, should they have unused fireworks after the display. They would be forced to park the CMVs carrying Division 1.3G and 1.4G products in areas less secure than the motor carrier's home base.

IV. Method To Ensure an Equivalent or Greater Level of Safety

As a condition for maintaining the exemption, each motor carrier would be required to notify FMCSA within 5 business days of any crash (as defined in 49 CFR 390.5) involving the operation of any CMVs under this exemption. The applicants advise they have never been involved in a crash.

In the exemption request, the applicants assert that the operational demands of this unique industry minimize the risks of CMV crashes. In the last few days before the Independence Day holiday, these drivers transport fireworks over relatively short routes from distribution points to the site of the fireworks display and normally do so in the early morning when traffic is light. The applicants noted that during the 2015 Independence Day season, the farthest Illumination Fireworks traveled from its home base was 150 miles. At the site, drivers spend considerable time installing, wiring, and checking the safety of fireworks, followed by several hours of duty in the late afternoon and early evening prior to the event. Before beginning another duty day, these drivers must take 10 consecutive hours off duty, the same as other CMV drivers.

V. Public Comments

On March 16, 2016, FMCSA published notice of this application, and asked for public comment (81 FR 14208). One comment was received; Advocates for Highway and Auto Safety (Advocates) opposed the exemption.

Advocates said it "objects to the granting of the present exemption on the same policy and safety grounds detailed in prior comments regarding similar applications for exemption filed by the American Pyrotechnics Association and the original application filed by the applicants." Advocates pointed out that Illumination Fireworks' out-of-service (OOS) rate for vehicles was 61 percent above the national average; for drivers more than 5 times the national average; and for hazardous materials nearly 6.5 times the national average. It also noted that Illumination Fireworks was cited for three violations on June 28, 2014, the first day of the previous exemption; two of the violations resulted in OOS orders. Similarly, Advocates described ACE Pyro's vehicle OOS rate as double the national average and its driver OOS rate as more than 3.5 times the national average. Advocates stated that, "Motor carriers of hazardous materials with less than exemplary safety records, such as these petitioners, should not be granted an exemption from the federal safety and hours of service requirements that have been specifically adopted to ensure operating safety on our public roads and highways."

All comments are available for review in the docket for this notice.

VI. FMCSA Response to Public Comments and Agency Decision

The Agency comprehensively investigates the safety history of each applicant during the review process. Prior to publishing a **Federal Register** notice announcing the receipt of an exemption request, FMCSA ensures that the motor carriers involved have a current USDOT registration, Hazardous Materials Safety Permit (if required), minimum required levels of insurance, and are not subject to any "imminent hazard" or other OOS orders. The rating of the carrier in the Agency's Safety Management System (SMS) is considered. FMCSA has reviewed these safety records, including inspection and accident reports, for the applicants. The Agency also requested and received a records review of each carrier from the Pipeline and Hazardous Materials Safety Administration (PHMSA). None of these records reflected decisive negative information about the applicants' safety performance or status. Each applicant has a "satisfactory" safety rating.

The OOS records of Illumination Fireworks and ACE Pyro, as described by the Advocates, are not representative of the safety record of these carriers. Because of the small numbers of inspections on record for the applicants, the OOS rates are not a valid basis for comparison with industry-wide averages. For example, a carrier having only three inspections, with one of those including a driver OOS violation, would have a driver OOS rate of 33% compared to the National average for inspected drivers of approximately 5%. Under those circumstances, FMCSA would not consider the apparently high OOS rate to be particularly significant.

The June 28, 2014 inspection of Illumination cited by Advocates occurred nearly 2 years ago. The OOS violations included a problem with the hazardous materials (HM) shipping papers and a driver with an improper class of CDL. Although serious, neither of these violations posed an imminent hazard since one was a paperwork violation and the driver cited for the other held a CDL with a hazardous materials endorsement. FMCSA considers 2 years of data when evaluating safety records. This inspection will no longer be within the 2-year period by the time this year's exemption period begins.

The two inspections of Ace Pyro on record occurred on different vehicles in 2015. In both instances, there were OOS problems with brakes and on one a driver with an improper class of CDL. Because Ace Pyro had no negative information in our review of its safety records that would warrant an unsatisfactory safety rating, FMCSA does not consider these two inspections to be a clear indicator of overall safety problems with this carrier.

The Agency believes that the applicants operating under the exemption will likely achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption [49 CFR 381.305(a)]. FMCSA therefore grants the requested exemptions for 5 years.

VII. Terms and Conditions of the Exemption

Period of the Exemption

The exemption from the requirements of 49 CFR 395.3(a)(2) is effective for the periods of June 28–July 8, 2016 through 2020.

Extent of the Exemption

The exemption is restricted to the drivers employed by the applicants. The drivers are exempt from the requirements of 49 CFR 395.3(a)(2). This regulation prohibits a driver from driving a CMV after the 14th hour after coming on duty and does not permit off-duty periods to extend the 14-hour limit. Drivers covered by the exemption may exclude off-duty and sleeper-berth time of any length from the calculation of the 14-hour limit. The exemption is contingent on each driver driving no more than 11 hours in the 14-hour period after coming on duty, as extended by any off-duty or sleeper-berth time. The exemption is further contingent on each driver having a minimum of 10 consecutive hours off duty prior to beginning a new duty period. Drivers operating under the exemption must carry a copy of this **Federal Register** notice or equivalent signed letter from FMCSA, and provide it to enforcement officers upon request. The carriers and drivers must comply with all other applicable requirements of the Federal Motor Carrier Safety Regulations (49 CFR parts 350–399) and Hazardous Materials Regulations (49 CFR parts 105–180).

Other Conditions

The exemption is contingent upon each carrier maintaining USDOT registration, a Hazardous Materials Safety Permit (if required), minimum levels of public liability insurance, and not being subject to any "imminent hazard" or other out-of-service (OOS) orders issued by FMCSA. Each driver covered by the exemption is required to maintain a valid CDL with the appropriate endorsements, not be subject to any suspension of driving privileges, and meet all physical qualifications required by 49 CFR part 391.

Preemption

In accordance with 49 U.S.C. 31313(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

FMCSA Accident Notification

Exempt motor carriers are required to notify FMCSA within 5 business days of any accident (as defined by 49 CFR 390.5) involving the operation of any of its CMVs while under this exemption. The notification must include the following information:

a. Exemption Identity: "Illumination Fireworks" or "Ace Pyro"

b. Name of operating motor carrier and USDOT number,

c. Date of the accident,

d. City or town, and State, in which the accident occurred, or closest to the accident scene,

e. Driver's name and driver's license number and State of issuance,

f. Vehicle number and State license plate number,

g. Number of individuals suffering physical injury,

h. Number of fatalities,

i. The police-reported cause of the accident,

j. Whether the driver was cited for violation of any traffic laws or motor carrier safety regulations, and

k. The driver's total driving time and total on-duty time period prior to the accident.

Accidents would be reported via email to *MCPSD@DOT.GOV.*

Issued on: June 27, 2016.

T.F. Scott Darling, III,

Acting Administrator.

[FR Doc. 2016–15798 Filed 6–29–16; 4:15 pm]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2007–28043]

Hours of Service (HOS) of Drivers; American Pyrotechnics Association (APA); Granting of Exemption From the 14-Hour Rule

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces the granting of an exemption for 51 member companies of the American Pyrotechnics Association (APA) from the hours-of-service (HOS) regulation prohibiting drivers of commercial motor vehicles (CMVs) from driving after the 14th hour after coming on duty. Fifty-one APA members currently hold such exemptions. APA requests discontinuance of the exemption for 4 carriers, and new exemptions for 4 carriers, with the total therefore remaining at 51. The "Fixing America's Surface Transportation Act" (FAST Act) extended the HOS exemptions in effect on the date of enactment of that Act to 5 years from the date of issuance. Because the FAST Act also authorized new exemptions for a period of up to 5 years, the Agency grants 4-year exemptions to 4 additional fireworks companies, ensuring that all 51 exemptions will terminate on July 8, 2020. FMCSA has determined that the terms and conditions of the exemption ensure a level of safety equivalent to, or greater than, the level of safety achieved without the exemption.

DATES: These exemptions from 49 CFR 395.3(a)(2) are effective from June 28 through July 8, at 11:59 p.m. local time, each year through 2020.

ADDRESSES:

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: (202) 366–4325. Email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, "FMCSA–2007–28043" in the "Keyword" box and click "Search." Next, click "Open Docket Folder" button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption, and explain its terms and conditions. The exemption may be renewed (49 CFR 381.300(b)).

Section 5206(a)(3) of the FAST Act amended 49 U.S.C. 31315 to permit FMCSA to grant exemptions for up to 5 years from the date of issuance, instead of the previous two years [section 31315(b)(2)]. This statutory provision will be codified in 49 CFR part 381 in a forthcoming rulemaking. Section 5206(b)(2)(A) of the FAST Act also extended all HOS exemptions in effect on the date of enactment to a period of 5 years from the date of issuance. FMCSA announced the extension of the HOS fireworks exemption in a **Federal Register** notice published on May 9, 2016 [81 FR 28115].

III. APA Application for Exemption

The HOS rule in 49 CFR 395.3(a)(2) prohibits the driver of a property-carrying CMV from driving after the 14th hour after coming on duty following 10 consecutive hours off duty. The APA, a trade association representing the domestic fireworks industry, was granted an exemption for 51 member companies for the 2015 and 2016 Independence Day periods [80 FR 37040, June 29, 2015]. APA has requested new exemptions for four carriers and discontinuance of the exemptions for four carriers,[1] maintaining the total at 51. As mentioned above, the 51 exemptions granted to APA members in 2015 (now reduced to 47 exemptions) were extended, pursuant to section 5206(b)(2)(A) of the FAST Act, through the annual Independence Day periods ending on July 8, 2020. The exemptions for the 4 new APA carriers will also expire on July 8, 2020. Although this is less than the 5-year exemption period authorized by 49 U.S.C. 31315(b)(2), as amended by section 5206(a)(3) of the FAST Act, FMCSA believes that the interests of the APA members and the Agency would best be served by harmonizing, as far as possible, the expiration dates of all such fireworks-related exemptions. It should also be noted that section 5206(b)(2)(A) of the FAST Act extends HOS exemptions in effect on the date of enactment "for a period of 5 years *from the date such exemption was granted*" (emphasis added). FMCSA believes that the intent of the statute was to extend the effective period of an exemption from 2 to 5 years, on the assumption that exemptions begin upon issuance and remain in effect (in most cases) for 2 consecutive years. Since the 2015 fireworks exemption involved 2 separate periods, both ending after "the date such exemption was granted," the Agency believes the FAST Act amendment is best interpreted as extending the end date of the fireworks exemption—namely July 8 of each year—through 2020. Like the other 47 APA companies that operated under the 2015 exemption, the 4 additional companies would be subject to all of the terms and conditions of the exemption.

The original APA application for relief from the 14-hour rule was submitted in 2004; a copy is in the docket. That application fully describes the nature of the pyrotechnic operations of the CMV drivers during a typical Independence Day period.

As stated in the 2004 request, the CMV drivers employed by APA members are trained pyro-technicians who hold commercial driver's licenses (CDLs) with hazardous materials (HM) endorsements. They transport fireworks and related equipment by CMVs on a very demanding schedule during a brief Independence Day period, often to remote locations. After they arrive, the drivers are responsible for set-up and staging of the fireworks shows.

The APA states that it is seeking an exemption for an additional four member companies because compliance with the current 14-hour rule in 49 CFR 395.3(a)(2) would impose a substantial economic hardship on numerous cities, towns and municipalities, as well as its member companies. To meet the demand for fireworks without the exemption, APA states that its member companies would be required to hire a second driver for most trips. The APA advises that the result would be a substantial increase in the cost of the fireworks shows—beyond the means of many of its members' customers—and that many Americans would be denied this important component of the celebration of Independence Day. The 47 APA member companies currently exempt, as well as the four carriers seeking an exemption for the first time, are listed in an appendix to this notice. The four new carriers are identified with an asterisk. A copy of the request for the exemption is included in the docket referenced at the beginning of this notice.

IV. Method To Ensure an Equivalent or Greater Level of Safety

The APA believes that the new exemptions would not adversely affect the safety of the fireworks transportation provided by these motor carriers. According to APA, its member-companies have operated under this exemption for 10 previous Independence Day periods without a reported motor carrier safety incident. Moreover, it asserts, without the extra time provided by the exemption, safety would decline because APA drivers would be unable to return to their home base after each show. They would be forced to park the CMVs carrying unused fireworks (HM 1.1G, 1.3G and 1.4G products) in areas less secure than the motor carrier's home base. As a condition of holding the exemption, each motor carrier would be required to notify FMCSA within five business days of any accident (as defined in 49 CFR 390.5) involving the operation of any of its CMVs while under this exemption. To date, FMCSA has received no accident notifications, nor is the Agency aware of any accidents reportable under terms of the prior APA exemptions.

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[1] Colonial Fireworks, DOT 177274; Fireworks West Internationale, DOT 245423; USA Halloween Planet Inc. dba USA Fireworks, DOT 725457; Western Fireworks Inc., DOT 838585.

In its exemption request, APA asserted that the operational demands of this unique industry minimize the risks of CMV crashes. In the last few days before July 4, these drivers transport fireworks over relatively short routes from distribution points to the site of the fireworks display, and normally do so in the early morning when traffic is light. At the site, they spend considerable time installing, wiring, and safety-checking the fireworks displays, followed by several hours off duty in the late afternoon and early evening prior to the event. During this time, the drivers are able to rest and nap, thereby reducing or eliminating the fatigue accumulated during the day. Before beginning another duty day, these drivers must take 10 consecutive hours off duty, the same as other drivers of property-carrying CMVs.

V. Public Comments

On May 9, 2016, FMCSA published notice of this application and requested public comments (81 FR 28115). Two comments were submitted, both opposing the exemption. The first was from an individual who objected to the exemption in principle, stating "I find it hypocritical of the FMCSA to consider exemptions to the hours of service regulations for any special interests." The second comment, from the Advocates for Highway and Auto Safety (Advocates), listed objections to 19 of the 51 carriers. Of these 19, two were among the four carriers proposed to be added to this exemption. In most cases, Advocates pointed out the carrier had out-of-service (OOS) rates well above the national averages. Advocates also described violations that were found during roadside inspections of the carriers. Further, they asserted that FMCSA had not conducted thorough safety-record checks of the carriers because the OOS rates and inspection violations were not mentioned in the May 9, 2016, **Federal Register** notice (81 FR 28115).

FMCSA Response

Section 5206(b)(2)(A) of the FAST Act extended HOS exemptions in effect on the date of enactment "for a period of 5 years from the date such exemption was granted." Therefore, the exemptions of the 47 carriers that were included in the previous exemption period have been statutorily extended until July 8, 2020 [81 FR 28115].

Prior to the time exemption applications are announced in the **Federal Register**, FMCSA checks basic elements of safety records for any factors that would disqualify the carrier, such as being under an Imminent Hazard Order. Other elements of the safety records are checked during the comment period of the notice. The information provided by Advocates for each carrier was also identified by FMCSA during the comment period and has been considered in this final determination for the four new applicant-carriers.

With regard to safety statistics, none of the 51 carriers granted exemptions in 2015 (which were extended by the FAST Act) or the 4 carriers proposed for exemption in 2016, was under an OOS or Imminent Hazard Order, had any alerts in the Safety Management System (SMS), or was under investigation by the Pipeline and Hazardous Materials Safety Administration. All had "satisfactory" safety ratings based on compliance reviews, and all had valid Hazardous Materials Safety Permits. A few "acute critical" violations attributed to 3 of the carriers occurred months after the Independence Day holiday, when the carriers were not operating under the exemption. Because of the small numbers of inspections on record for most of these carriers, the OOS rates cited by Advocates do not constitute a statistically reliable basis for a comparison with national averages. For example, a carrier having only three inspections, one of which included a driver OOS violation, would have a driver OOS rate of 33% compared to the national average of approximately 5%. Under those circumstances, FMCSA would not consider the apparent high OOS rate to be particularly significant.

Carrier Pyrotecnico LLC, USDOT 548303, was identified as not having a valid registration with FMCSA. However, investigation of the carrier's MCS–150B registration documents indicated that the carrier's officials had mistakenly used the same USDOT number when intending to apply for new registration of a different carrier. The carrier is reportedly undertaking a correction of the records. The Agency considers Pyrotecnico LLC, USDOT 526749, to be registered and included in the exemptions extended by the FAST Act.

In light of the above, FMCSA believes that the fireworks carriers previously granted HOS exemptions remain likely, as before, to achieve a level of safety equivalent to or greater than the level that compliance with the 14-hour rule would ensure. Similarly, the Agency has concluded that the 4 APA members applying for the same HOS exemption would likely meet the same standard and has decided to grant them a 4-year exemption from the 14-hour rule.

VI. Terms and Conditions of the Exemption

Period of the Exemption

The exemption from 49 CFR 395.3(a)(2) is effective from June 28 through July 8, at 11:59 p.m. local time, each year through 2020 for the 51 carriers identified in this notice.

Terms and Conditions of the Exemption

The exemptions from 49 CFR 395.3(a)(2) will be limited to drivers employed by the 47 motor carriers already covered by the exemption, and drivers employed by 4 motor carriers that were not included for the 2015 period. The four carriers are identified by an asterisk in the appendix table of this notice. Section 395.3(a)(2) prohibits a driver from driving a CMV after the 14th hour after coming on duty and does not permit off-duty periods to extend the 14-hour limit. Drivers covered by this exemption may exclude off-duty and sleeper-berth time of any length from the calculation of the 14-hour limit. This exemption is contingent on each driver driving no more than 11 hours in the 14-hour period after coming on duty, as extended by any off-duty or sleeper-berth time in accordance with this exception. The exemption would be further contingent on each driver having a full 10 consecutive hours off duty following 14 hours on duty prior to beginning a new driving period. Drivers operating under the exemption must carry a copy of this **Federal Register** notice or equivalent signed letter from FMCSA, and provide it to enforcement officers upon request. The carriers and drivers must comply with all other applicable requirements of the Federal Motor Carrier Safety

Regulations (49 CFR parts 350–399) and Hazardous Materials Regulations (49 CFR parts 105–180).

Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

FMCSA Notification

Exempt motor carriers would be required to notify FMCSA within 5 business days of any accidents (as defined by 49 CFR 390.5) involving the operation of any of their CMVs while under this exemption. The notification must include the following information:

a. Name of the exemption: ''APA,''

b. Date of the accident,

c. City or town, and State, in which the accident occurred, or which is closest to the scene of the accident,

d. Driver's name and driver's license number,

e. Vehicle number and State license number,

f. Number of individuals suffering physical injury,

g. Number of fatalities,

h. The police-reported cause of the accident,

i. Whether the driver was cited for violation of any traffic laws, or motor carrier safety regulations, and

j. The total driving time and the total on-duty time of the CMV driver at the time of the accident.

Termination

The FMCSA does not believe the motor carriers and drivers covered by this exemption will experience any deterioration of their safety record. However, should this occur, FMCSA will take all steps necessary to protect the public interest, including revocation of the exemption. The FMCSA will immediately revoke the exemption for failure to comply with its terms and conditions. Exempt motor carriers and drivers are subject to FMCSA monitoring while operating under this exemption.

Issued on: June 27, 2016.

T.F. Scott Darling, III,

Acting Administrator.

Appendix to Notice of Application for Approval of Motor Carriers To Utilize American Pyrotechnics Association's (APA) Exemption From the 14-Hour Rule During 2016 Independence Day Celebrations

Motor carrier	Street address	City, state, zip code	DOT No.
1. American Fireworks Company	7041 Darrow Road	Hudson, OH 44236	103972
2. American Fireworks Display, LLC	P.O. Box 980	Oxford, NY 13830	2115608
3. AM Pyrotechnics, LLC	2429 East 535th Rd	Buffalo, MO 65622	1034961
4. Arthur Rozzi Pyrotechnics	6607 Red Hawk Ct	Maineville, OH 45039	2008107
5. Atlas PyroVision Entertainment Group, Inc	136 Old Sharon Rd	Jaffrey, NH 03452	789777
6. Central States Fireworks, Inc	18034 Kincaid Street	Athens, IL 62613	1022659
7. East Coast Pyrotechnics, Inc	4652 Catawba River Rd	Catawba, SC 29704	545033
8. Entertainment Fireworks, Inc	13313 Reeder Road SW	Tenino, WA 98589	680942
9. Falcon Fireworks	3411 Courthouse Road	Guyton, GA 31312	1037954
10. Fireworks & Stage FX America	12650 Hwy 67S. Suite B	Lakeside, CA 92040	908304
11. Fireworks by Grucci, Inc	20 Pinehurst Drive	Bellport, NY 11713	324490
12. *Flashing Thunder Fireworks dba Legal Aluminum King Mtg.	700 E Van Buren Street	Mitchell, IA 50461	420413
13. J&J Computing dba Fireworks Extravaganza	174 Route 17 North	Rochelle Park, NJ 07662	2064141
14. Gateway Fireworks Displays	P.O. Box 39327	St Louis, MO 63139	1325301
15. Great Lakes Fireworks	24805 Marine	Eastpointe, MI 48021	1011216
16. Hamburg Fireworks Display, Inc	2240 Horns Mill Road SE	Lancaster, OH	395079
17. Hawaii Explosives & Pyrotechnics, Inc	17–7850 N. Kulani Road	Mountain View, HI 96771	1375918
18. Hollywood Pyrotechnics, Inc	1567 Antler Point	Eagan, MN 55122	1061068
19. Homeland Fireworks, Inc	P.O. Box 7	Jamieson, OR 97909	1377525
20. Island Fireworks Co., Inc	N1597 County Rd VV	Hager City, WI 54014	414583
21. J&M Displays, Inc	18064 170th Ave	Yarmouth, IA 52660	377461
22. Lantis Fireworks, Inc	130 Sodrac Dr., Box 229	N. Sioux City, SD 57049	534052
23. Legion Fireworks Co., Inc	10 Legion Lane	Wappingers Falls, NY 12590	554391
24. Miand Inc. dba Planet Productions (Mad Bomber)	P.O. Box 294, 3999 Hupp Road.	Kingsbury, IN 46345	777176
25. Martin & Ware Inc. dba Pyro City Maine & Central Maine Pyrotechnics.	P.P. Box 322	Hallowell, ME 04347	734974
26. Melrose Pyrotechnics, Inc	1 Kinsgubury Industrial Park	Kingsbury, IN 46345	434586
27. Precocious Pyrotechnics, Inc	4420–278th Ave NW	Belgrade, MN 56312	435931
28. *Pyro Shows, Inc	115 N 1st Street	LaFollette, TN 37766	456818
29. Pyro Shows of Texas, Inc	6601 9 Mile Azle Rd	Fort Worth, TX 76135	2432196
30. *Pyro Engineering Inc., dba/Bay Fireworks	400 Broadhollow Rd. Ste #3	Farmindale, NY 11735	530262
31. Pyro Spectaculars, Inc	3196 N Locust Ave	Rialto, CA 92376	029329
32. Pyro Spectaculars North, Inc	5301 Lang Avenue	McClellan, CA 95652	1671438
33. Pyrotechnic Display, Inc	8450 W. St. Francis Rd	Frankfort, IL 60423	1929883
34. Pyrotecnico (S. Vitale Pyrotechnic Industries, Inc.)	302 Wilson Rd	New Castle, PA 16105	526749
35. Pyrotecnico, LLC	60 West Ct	Mandeville, LA 70471	548303
36. Pyrotecnico FX	6965 Speedway Blvd. Suite 115.	Las Vegas, NV 89115	1610728
37. Rainbow Fireworks, Inc	76 Plum Ave	Inman, KS 67546	1139643
38. RES Specialty Pyrotechnics	21595 286th St	Belle Plaine, MN 56011	523981
39. Rozzi's Famous Fireworks, Inc	11605 North Lebanon Rd	Loveland, OH 45140	0483686
40. *Sky Wonder Pyrotechnics, LLC	3626 CR 203	Liverpool, TX 77577	1324580
41. Skyworks, Ltd	13513 W. Carrier Rd	Carrier, OK 73727	1421047

APPENDIX TO NOTICE OF APPLICATION FOR APPROVAL OF MOTOR CARRIERS TO UTILIZE AMERICAN PYROTECHNICS ASSOCIATION'S (APA) EXEMPTION FROM THE 14-HOUR RULE DURING 2016 INDEPENDENCE DAY CELEBRATIONS—Continued

Motor carrier	Street address	City, state, zip code	DOT No.
42. Sorgi American Fireworks Michigan, LLC	935 Wales Ridge Rd	Wales, MI 48027	2475727
43. Spielbauer Fireworks Co, Inc	220 Roselawn Blvd	Green Bay, WI 54301	046479
44. Spirit of 76	6401 West Hwy 40	Columbia, MO 65202	2138948
45. Starfire Corporation	682 Cole Road	Carrolltown, PA 15722	554645
46. Vermont Fireworks Co., Inc./Northstar Fireworks Co., Inc.	2235 Vermont Route 14 South	East Montpelier, VT 05651	310632
47. Western Display Fireworks, Ltd	10946 S. New Era Rd	Canby, OR 97013	498941
48. Western Enterprises, Inc	P.O. Box 160	Carrier, OK 73727	203517
49. Wolverine Fireworks Display, Inc	205 W Seidlers	Kawkawlin, MI	376857
50. Young Explosives Corp	P.O. Box 18653	Rochester, NY 14618	450304
51. Zambelli Fireworks MFG, Co., Inc	P.O. Box 1463	New Castle, PA 16103	033167

* Not included in 2015 list of approved carriers.

[FR Doc. 2016–15797 Filed 6–29–16; 4:15 pm]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Fourth Allocation of Public Transportation Emergency Relief Funds in Response to Hurricane Sandy

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: The Federal Transit Administration (FTA) announces the allocation of $834,612,566 through the Public Transportation Emergency Relief Program (Emergency Relief Program, Catalogue of Federal Domestic Assistance #20.527) for recovery projects to three FTA recipients with estimated damages that exceed the amounts of funding previously made available: The Metropolitan Transportation Authority of New York, the New Jersey Transit Corporation, and the Port Authority of New York and New Jersey. Funds allocated in this notice are in addition to funds allocated on March 29, 2013 (78 FR 19357), May 29, 2013 (78 FR 32296), and November 5, 2014 (79 FR 65762), and brings the total amount of Hurricane Sandy Emergency Relief funds allocated by FTA to date to $10.088 billion. Of that amount, $5,196,184,125 has been allocated for emergency response, recovery, and rebuilding projects and $4,891,883,625 has been allocated for resilience projects, which are designed to protect transit systems in the Hurricane Sandy disaster area from damages associated with future storms. With this notice, FTA has now fully allocated all of the funding made available under the Disaster Relief Appropriations Act of 2013 (Appropriations Act, Pub. L. 113–2). FTA is allocating funds consistent with the requirements of the Appropriations Act, the FTA Emergency Relief Program 49 U.S.C. 5324, the Final Rule for the Emergency Relief Program, 49 CFR part 602, published in the **Federal Register** on October 7, 2014 (78 FR 23806), and all previously announced FTA policies and procedures for Hurricane Sandy Emergency Relief funding.

In addition, this notice establishes a procedure for recipients to request the reallocation of funding previously allocated for resilience projects to fund eligible disaster recovery expenses in excess of the total amount of funding available from previous allocations, insurance payments, and the expected local cost share. Funds reallocated under this procedure must be used for disaster recovery expenses or be returned to FTA upon completion of the recovery effort. Reallocation requests are subject to the terms and conditions specified in this notice and must be approved by FTA.

Unless specifically revised by this notice, all previously published program policies and requirements associated with Hurricane Sandy recovery and rebuilding funding remain in effect.

FOR FURTHER INFORMATION CONTACT: Contact the appropriate FTA Regional Office found at *http://www.fta.dot.gov* for application-specific information and other assistance needed in preparing an FTA grant application. For program-specific questions, please contact Adam Schildge, Office of Program Management, 1200 New Jersey Ave. SE., Washington, DC 20590, phone: (202) 366–0778, or email, *Adam.Schildge@dot.gov.* For legal questions, contact Helen Serassio, Office of Chief Counsel, same address, phone: (202) 366–1974, or email, *Helen.Serassio@dot.gov.*

SUPPLEMENTARY INFORMATION:

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I. Allocation of Hurricane Sandy Recovery Funding
II. Procedure for Reallocation of Resilience Funds for Disaster Recovery
III. Award Administration

I. Allocation of Hurricane Sandy Recovery Funding

The FTA Emergency Relief (ER) Program provides FTA with the authority to reimburse emergency response and recovery costs for public transportation systems, including costs for projects to protect systems in danger of future damage (resilience projects), after an emergency or major disaster. The Disaster Relief Appropriations Act provides $10.9 billion for FTA's Emergency Relief Program for recovery, relief, and resilience efforts in areas affected by Hurricane Sandy. However, as a result of the Balanced Budget and Emergency Deficit Control Act of 2011 (Pub. L. 112–25) for fiscal year (FY) 2013, approximately five percent, or almost $545 million of the $10.9 billion, was subject to sequestration and is unavailable for Hurricane Sandy disaster relief, leaving approximately $10.349 billion available. In addition, $185 million was transferred to the Federal Railroad Administration (FRA) leaving a balance of $10.164 billion. FTA has allocated the available funding in multiple tiers for emergency response, recovery and rebuilding, locally-prioritized resilience projects, competitively selected resilience projects, and through direct transfers to other DOT offices.

Purpose of allocation	Amount allocated
Response, Recovery and Rebuilding (including $834 million in this notice)	$5,196,184,125
Locally-Prioritized Resilience	1,300,000,000

Purpose of allocation	Amount allocated
Competitive Resilience	3,591,883,625
Total Allocations	[1] 10,088,067,750

[1] An additional $76,232,250 is available for oversight/administrative expenses for a total of $10,164,300,000.

With this notice, FTA is allocating the remaining $834.6 million in available recovery funding on a proportional basis, based on previous FTA recovery allocations and detailed damage assessments submitted by the affected agencies that were prepared in cooperation with FTA and Federal Emergency Management Administration (FEMA) staff, including recently validated updates to these estimates. The damage assessments completed in the immediate aftermath of Hurricane Sandy estimated a recovery and rebuilding cost of $5.83 billion. During the summer of 2015, FTA was notified by three of the affected transit agencies that the estimated cost of recovery and rebuilding has increased due to previously unknown latent damages, refinement of the cost estimates for recovery capital projects, and changes in the construction market since the original damage estimates were submitted. FTA required submission of the revised cost estimates by August 14, 2015. Based on those submittals, FTA independently verified the validity of proposed increases, and has determined that the estimated total cost of repairing the damage has increased by approximately $2.1 billion to a revised total estimated $7.9 billion.

As this is the final allocation of funds, FTA is allocating these funds proportionally based on the current estimated unfunded recovery need for each agency, which takes into account the current revised estimated damage assessments as well as funds that have previously been allocated. Consistent with previous allocations and program policies, recovery funding allocated in this notice can be used for eligible recovery expenses in accordance with the Emergency Relief program requirements. This includes the recovery costs of transportation assets owned by other entities, to the extent those assets are used for public transportation purposes, and in a proportion consistent with written agreement(s) between the public transit agency and the owner of the asset.

The approximately $834.6 million allocated in this notice includes approximately $817 million that was reserved for future allocation and a remaining balance of $17.473 million from the approximately $28 million that FTA set aside in the March 29, 2013, **Federal Register** Notice of Allocation. Prior to determining the allocation amounts in this notice, FTA solicited requests for outstanding Hurricane Sandy disaster relief needs from other affected transit agencies. Based on the responses received, FTA has determined that there are no remaining disaster recovery needs beyond the three agencies included in this notice.

FEDERAL TRANSIT ADMINISTRATION FTA SECTION 5324 EMERGENCY RELIEF PROGRAM

[Allocations for Hurricane Sandy recovery, by agency *]

State(s)	Agency	Discretionary funding ID (current allocation)	Previous recovery allocations	Additional recovery and restoration	Total allocations
NY	New York Metropolitan Transportation Authority.	D2016–SAND–003	$2,896,771,774	$432,019,737	$3,328,791,511
NY, NJ	Port Authority of New York and New Jersey.	D2016–SAND–004	1,073,024,652	299,760,847	1,372,785,499
NJ	New Jersey Transit Corporation	D2016–SAND–005	341,990,757	102,831,982	444,822,739
Mult	Other affected agencies		49,784,376	0	49,784,376
Grand total			4,361,571,559	834,612,566	5,196,184,125

* Allocation amounts reflect reductions due to sequestration. Recovery funds include capital and operating assistance

II. Procedure for Reallocation of Resilience Funds for Disaster Recovery

A. Policy

FTA has determined that certain transit agencies have estimated total recovery and rebuilding costs that exceed the amount of funding made available for disaster recovery under the FTA ER Program. These damage estimates have increased due to the discovery of latent damages, refinement to project cost estimates, and changes in the construction market since the original estimates were submitted. The need for Federal assistance has also increased due to the use by recipients of statutory alternatives to local cost sharing and the undetermined status of insurance proceeds. Additionally, FTA has previously allocated funding to these agencies for resilience projects designed to protect the transit systems from damages associated with future natural disasters; however, a portion of this resilience funding has not yet been obligated or disbursed.

Based on a review of the remaining unfunded disaster recovery needs, FTA will allow recipients the option to request a reallocation of unliquidated resilience funding for their remaining unfunded disaster recovery expenses.

Each agency may request the reallocation of resilience funds up to a maximum amount that is based on most recent damage cost estimates submitted by the agencies as of August 14, 2015, and validated by FTA, insurance payments that have been received to date, and an expectation that agencies will provide a local cost share equal to at least 10 percent of the total cost of Hurricane Sandy disaster recovery. The estimated maximum amount each agency may request to reallocate for FTA ER funding is shown in the table below. However, these amounts may increase or decrease based on additional validated recovery costs and/or the receipt of additional insurance proceeds.

Agency	Estimated maximum amount of resilience funds that may be reallocated ($ million)
MTA–NY	800.7
Port Authority	466.6
New Jersey Transit	187.6

A transit agency's request for reallocation of resilience funds may include eligible repair work to transportation assets not owned by the transit agency, but used by it, if the transit agency provides documentation that: Demonstrates that the damage was caused by Hurricane Sandy; that the asset is used for public transportation purposes; and; that the proposed share of the project cost is consistent with written agreement(s) between the public transit agency and the owner of the asset.

In determining whether to approve a reallocation request, FTA will review the eligibility of the proposed project for Hurricane Sandy recovery funding. The reallocation request must include information sufficient for FTA to make the following determinations:

- The proposed project is a capital recovery project that addresses damage caused directly by Hurricane Sandy.
- The proposed recovery project is documented in previously validated damage estimates (original or revised) or in new documentation demonstrating that the damage was caused by Hurricane Sandy.
- For proposed recovery projects that include costs associated with repairing transportation assets owned by other entities, the applicant must provide documentation showing that the asset is used for public transportation purposes, and that the proposed share of the project cost is consistent with written agreement(s) between the public transit agency and the owner of the asset.
- The proposed recovery project complies with the Appropriations Act, the FTA's Emergency Relief Program Final Rule and applicable FTA guidance.
- If funds will be reallocated from a resilience project for which FTA has disbursed funding, the applicant must demonstrate that that the funds disbursed to date will support a resilience project of independent utility, consistent with the scope of the competitive funding application if applicable.
- The request must also include documentation explaining why the applicant has prioritized the recovery project over the resilience project.

The eligibility of recovery projects for reallocated funding is consistent with previous eligibilities for recovery funding under this program. Funds reallocated under this procedure may only be used for the recovery project or projects listed in the reallocation request.

B. Requirements

Agencies that wish to request a reallocation of resilience funds must provide:

- The name, location, and description of the recovery project(s) for which funds are requested to be reallocated to.
- Documentation identifying the project in the most recent validated Hurricane Sandy damage assessment, or if new, documentation showing that the project is an eligible disaster recovery expense resulting directly from damages caused by Hurricane Sandy. Such documentation may include FEMA draft project worksheets from the period immediately after the disaster, engineering estimates that indicate the source of damages and the scope and projected cost of necessary repair work, or other similar documents.
- A statement why the requested project is a priority over the resilience project losing the funds.
- The source of resilience funds (local priority resilience or competitive resilience) that will be returned to the program, as well as the location and description of any resilience project(s) from which funds will be withdrawn and the status of those projects.
- If applicable, a copy of the subject agreement with a third party entity if the proposed project includes an asset owned by a third party, including the methodology for determining the allocation of costs associated with repairing the relevant asset.
- If FTA funds have been disbursed for a resilience project from which the agency proposes to return funds for reallocation, the application must indicate the amount of funds not disbursed for the project, the amount of those funds to be retained for additional work on the project, the status of the project, and an explanation of whether or how any funds retained and the disbursed funds will be used to complete a resilience project with independent utility.

All requests for reallocation of funds for recovery projects must be submitted to FTA no later than September 30, 2016. All requests must be submitted through the FTA Emergency Relief docket under FTA–2016–0001. FTA will post the agency response to reallocation requests to the docket.

III. Coordination With the Federal Emergency Management Agency (FEMA)

The Disaster Relief Appropriations Act of 2013 appropriated funding to FTA for transit systems affected by Hurricane Sandy, and a Memorandum of Agreement between FTA and FEMA establishes FTA as the primary payor of expenses incurred by public transportation agencies as a result of a major disaster. FTA and FEMA continue to coordinate on funding for Sandy damages, and FEMA has advised that where FTA has made available funding that by FTA's estimation fully satisfies the Federal share of 90% of the maximum amount of funding needed for public transit disaster recovery expenses required by Hurricane Sandy damage, additional funding from FEMA is not eligible.

IV. Award Administration

All previously published program policies and requirements associated with Hurricane Sandy recovery and rebuilding funding remain in effect.

Issued in Washington, DC.

Carolyn Flowers,

Acting Administrator.

[FR Doc. 2016–15801 Filed 7–1–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

U.S. Merchant Marine Academy Board of Visitors Meeting

AGENCY: Maritime Administration, DOT.

ACTION: Meeting notice.

SUMMARY: The U.S. Department of Transportation, Maritime Administration (MARAD) announces that the following U.S. Merchant Marine Academy ("Academy") Board of Visitors (BOV) meeting will take place:

1. *Date:* July 13, 2016.
2. *Time:* 1:30 p.m.
3. *Location:* Capital Visitors Center, Washington, DC. Room to be determined.
4. *Purpose of the Meeting:* The purpose of this meeting is to brief BOV members on the Academy Advisory Board's annual report to the Secretary of Transportation and the status of reaccreditation.
5. *Public Access to the Meeting:* This meeting is open to the public. Seating is on a first-come basis. Members of the public wishing to attend the meeting will need to show photo identification in order to gain access to the meeting location.

FOR FURTHER INFORMATION CONTACT: The BOV's Designated Federal Officer and Point of Contact Brian Blower; 202 366–2765; *Brian.Blower@dot.gov.*

SUPPLEMENTARY INFORMATION: Any member of the public is permitted to file a written statement with the Academy BOV. Written statements should be sent to the Designated Federal Officer at: Brian Blower; 1200 New Jersey Ave SE., W28–313, Washington, DC 20590 or via email at *Brian.Blower@dot.gov.* (Please contact the Designated Federal Officer for information on submitting comments via fax.) Written statements must be received no later than three working days prior to the next meeting in order to provide time for member consideration. By rule, no member of the public attending open meetings will be allowed to present questions from the floor or speak to any issue under consideration by the BOV.

Authority: 46 U.S.C. 51312; 5 U.S.C. app. 552b; 41 CFR parts 102–3.140 through 102–3.165.

By Order of the Maritime Administrator.

Dated: June 28, 2016.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2016–15745 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Meeting Notice—U.S. Maritime Transportation System National Advisory Committee

AGENCY: Maritime Administration, Department of Transportation

ACTION: Notice of advisory committee name change and public meeting.

SUMMARY: The Maritime Administration (MARAD) announces that the name of the U.S. Marine Transportation System National Advisory Council has been changed to the U.S. Maritime Transportation System National Advisory Committee (MTSNAC or Committee). Furthermore, MARAD announces a public meeting of the MTSNAC to discuss advice and recommendations for the U.S. Department of Transportation on issues related to the maritime transportation system. Issues the MTSNAC will consider during this meeting include: Impediments to short sea transportation; expanding international gateway ports, using waterborne transportation to increase mobility throughout the domestic transportation system; modernizing the U.S. maritime workforce; strengthening maritime capabilities; and, encouraging maritime innovation.

DATES: The meeting will be held on Tuesday, July 19, 2016 from 8:00 a.m. to 5:00 p.m. and Wednesday, July 20, 2016 from 8:00 a.m. to 12:00 p.m. Eastern Daylight Saving Time (EDT).

ADDRESSES: The meeting will be held at the U.S. Department of Transportation, Federal Motor Carrier Safety Administration, National Training Center, 1310 North Courthouse Road, Suite 600, Arlington, VA 22201–2508.

FOR FURTHER INFORMATION CONTACT: Eric Shen, Co-Designated Federal Officer at: (202) 308–8968, or Jeffrey Flumignan, Co-Designated Federal Official at (212) 668–2064 or via email: *MTSNAC@dot.gov* or visit the MTSNAC Web site at *http://www.marad.dot.gov/ports/marine-transportation-system-mts/marine-transportation-system-national-advisory-committee-mtsnac/.*

SUPPLEMENTARY INFORMATION: The MTSNAC is a Federal advisory committee within MARAD that advises the U.S. Department of Transportation on issues related to the marine transportation system. The MTSNAC was originally established in 1999 and mandated in 2007 by the Energy Independence and Security Act of 2007. The MTSNAC operates in accordance with the provisions of the Federal Advisory Committee Act (FACA).

Agenda

The agenda will include: (1) Welcome, opening remarks and introductions; (2) formation of subcommittees or work groups; (3) development of work plans and proposed recommendations; (4) appointment of Vice Chair and (5) public comment. The meeting agenda will be posted on the MTSNAC Web site at *http://www.marad.dot.gov/ports/marine-transportation-system-mts/marine-transportation-system-national-advisory-committee-mtsnac/.*

The Maritime Administration requested that the MTSNAC consider the following issues for potential recommendations:

1. Impediments to effective use of short sea transportation, including America's Marine Highways (see, 46 CFR part 393), and methods to expand the use of the Marine Transportation System for freight and passengers;
2. Expanding the capacity of U.S. international gateway ports to accommodate larger vessels;
3. Improving waterborne transport to reduce congestion and increase mobility throughout the domestic transportation system;
4. Strengthening maritime capabilities essential to economic and national security;
5. Modernizing the maritime workforce and inspire and educate the next generation of mariners; and,
6. Driving maritime innovation.

In addition, the Maritime Administrator may request the MTSNAC to provide advice on other issues relating to the marine transportation system.

Public Participation

The meeting will be open to the public. Members of the public who wish to attend in person must RSVP to *MTSNAC@dot.gov* with your name and affiliation no later than 5:00 p.m. EDT on July 8, 2016, in order to facilitate entry. Seating will be extremely limited and available on a first-come-first-serve basis.

Services for Individuals with Disabilities: The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids are asked to notify Eric Shen at: (202) 308–8968, or Jeffrey Flumignan at (212) 668–2064 or *MTSNAC@dot.gov* five (5) business days before the meeting.

Written comments: Persons who wish to submit written comments for consideration by the Committee must email *MTSNAC@dot.gov,* or send them to MTSNAC Designated Federal Officers via email: *MTSNAC@dot.gov,* Maritime Transportation System National Advisory Committee, 1200 New Jersey Avenue SE., W21–307, Washington, DC 20590 no later than 5:00 p.m. EDT on July 8, 2016 to provide sufficient time for review.

Authority: 49 CFR part 1.93(a); 5 U.S.C. 552b; 41 CFR parts 102–3; 5 U.S.C. app. Sections 1–16.

By Order of the Maritime Administrator.

Dated: June 28, 2016.

Gabriel Chavez,

Secretary, Maritime Administration.

[FR Doc. 2016–15769 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0002; Notice 2]

Cooper Tire & Rubber Company, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Cooper Tire & Rubber Company (Cooper), has determined that certain Cooper tires do not fully comply with paragraph S5.5.1(b) of Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New pneumatic radial tires for light vehicles.* Cooper filed a report dated January 8, 2016, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Cooper then petitioned NHTSA under 49 CFR part 556 requesting a decision that the subject noncompliance is inconsequential to motor vehicle safety.

ADDRESSES: For further information on this decision contact Abraham Diaz, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–5310, facsimile (202) 366–5930.

SUPPLEMENTARY INFORMATION:

I. Overview

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Cooper submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of the petition was published, with a 30-day public comment period, on March 25, 2016 in the **Federal Register** (81 FR 16268). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/*. Then follow the online search instructions to locate docket number "NHTSA–2016–0002."

II. Tires Involved

Affected are approximately 338 Cooper Discoverer A/T3 size 265/70R18 Standard Load Tubeless Radial tires that were manufactured between September 27, 2015 and October 3, 2015.

III. Noncompliance

Cooper explains that the DOT serial week and year appears upside down and backwards in the tire identification number (TIN) molded into the outboard sidewalls of the subject tires and those tires therefore do not meet the requirements specified in paragraph S5.5.1 of FMVSS No. 139.

IV. Rule Text

Paragraph S5.5.1 of FMVSS No. 139 requires in pertinent part:

> S5.5.1 *Tire Identification Number.*
>
> . . .
>
> (b) *Tires manufactured on or after September 1, 2009.* Each tire must be labeled with the tire identification number required by 49 CFR part 574 on the intended outboard sidewall of the tire. Except for retreaded tires, either the tire identification number or a partial tire identification number, containing all characters in the tire identification number, except for the date code and, at the discretion of the manufacturer, any optional code, must be labeled on the other sidewall of the tire. Except for retreaded tires, if a tire does not have an intended outboard sidewall, the tire must be labeled with the tire identification number required by 49 CFR part 574 on one sidewall and with either the tire identification number or a partial tire identification number, containing all characters in the tire identification number except for the date code and, at the discretion of the manufacturer, any optional code, on the other side wall.

V. Summary of Cooper's Petition

Cooper believes that this noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Cooper submitted the following information and analysis of the subject noncompliance:

1. Cooper cited paragraph S5.5.1(b) of FMVSS No. 139, which requires tires manufactured on or after September 1, 2009 to be labeled with the TIN required by 49 CFR part 574 on the intended outboard sidewall of the tire.

2. Cooper also noted that 49 CFR 574.5 states that "[e]ach tire manufacturer shall conspicuously label on one sidewall of each tire it manufactures . . . a tire identification number containing the information set forth in paragraphs (a) through (d) of this section." The company further noted that 49 CFR 574.5(d) specifies that "[t]he fourth grouping, consisting of four numerical symbols, must identify the week and year of manufacture," with the first two symbols identifying the week and the last two identifying the year.

3. Cooper stated that the subject tires, on the outboard side only, were molded with an upside down and backwards DOT serial week and year. The serial number stamping should read: "DOT UPH4 1A6 3915." The outboard side, which includes the date code, was molded with the date code information oriented incorrectly upside down and backwards, which resulted in the characters being out of proper sequence.

4. Cooper explained that the existence of the stamping error was determined by visual examination of a subject tire on October 21, 2015 by warehouse personnel in Grand Prairie, TX. Upon further investigation, it was determined that only tires cured in one press location (E10L) during one production week (3915) were affected. Tires with the same SKU code were also curing in another press (Z11L), but these tires were stamped correctly. Cooper stated that sorting of its internal inventories revealed that for curing press E10L, during DOT serial week 3915, there was a total net cure of 518 tires, of which 180 tires have been accounted for in its warehouse. There were 338 tires distributed. Cooper made the final determination that a noncompliance exists as to those 338 tires on January 6, 2015.

5. Cooper states that the 338 subject tires do meet and/or exceed all performance requirements and all other labeling and marking requirements of FMVSS No. 139.

Furthermore, Cooper is not aware of any crashes, injuries, customer complaints, or field reports associated with the subject tires.

Cooper has informed NHTSA that the subject tires located in its inventory count reconciliation have been returned to the company's Findlay, OH plant, where they will be corrected prior to being released for sale.

In summation, Cooper believes that the described noncompliance is inconsequential to motor vehicle safety, and that its petition, to exempt Cooper from providing recall notification of the noncompliance, as required by 49 U.S.C. 30118, and remedying the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA'S Decision

NHTSA'S Analysis: The agency believes that in the case of a tire labeling noncompliance, one measure of its inconsequentiality to motor vehicle safety is whether the mislabeling would affect the manufacturer's or consumer's ability to identify the mislabeled tires properly, should the tires be recalled for performance related noncompliance. In this case, the nature of the labeling error does not prevent the correct identification of the affected tires. 49 CFR 574.5 requires the date code portion of the tire identification number to be placed in the last or correct position. In Cooper's case it is in the right-most position, however, the manufacturer date code is upside down. Because the label is located on the tire sidewall, it is not likely to be misidentified. A reader will be able to read the date code, by spinning the tire, and therefore inverting the date code will allow it to easily be read.

NHTSA'S Decision: In consideration of the foregoing, NHTSA finds that Cooper has met its burden of persuasion that the subject FMVSS No. 139 noncompliance in the affected tires is inconsequential to motor vehicle safety. Accordingly, Cooper's petition is hereby granted and Cooper is consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires that Cooper no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after Cooper notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2016–15750 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2016–0074]

Denial of Motor Vehicle Defect Petition

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a petition submitted to NHTSA under 49 U.S.C. 30162, requesting that the agency commence a proceeding to determine the existence of a defect related to motor vehicle safety in 2015 and 2016 Shasta Airflyte recreational vehicles. After a review of the petition and other information, NHTSA has concluded that all but one of the issues identified in the petition have been addressed through one of three other remedial actions. The one issue not addressed by another action was found not to represent an unreasonable risk to motor vehicle safety. The agency accordingly has denied the petition. The petition is hereinafter identified as DP15–008.

FOR FURTHER INFORMATION CONTACT: Mr. Nate Seymour, Medium & Heavy Duty Vehicle Division, Office of Defects Investigation (ODI), NHTSA, 1200 New Jersey Ave. SE., Washington, DC 20590. Telephone: (202) 366–2069.

SUPPLEMENTARY INFORMATION: By letter dated September 1, 2015, Mrs. Amy Green wrote to NHTSA requesting that the agency investigate eleven (11) issues identified in her letter.

NHTSA has reviewed the material provided by the petitioners and other pertinent data the agency gathered. The results of this review and NHTSA's analysis of the petition's merit is set forth in the DP15–008 Evaluation Report, appearing in the public docket referenced in the heading of this notice.

Forest River has recalled four (4) of the eleven (11) issues. One issue was addressed with a Technical Service Bulletin (TSB), five (5) were addressed in a consent order issued July 8, 2015 and it is unlikely that an order concerning notification and remedy of a safety-related defect would be issued as a result of granting Mrs. Amy Green's request for the one remaining issue. Therefore, an investigation into the issues raised by the petition does not appear to be warranted and the petition is denied.

Authority: 49 U.S.C. 30162(d); delegations of authority at CFR 1.95 and 501.8.

Gregory K. Rea,

Associate Administrator for Enforcement.

[FR Doc. 2016–15788 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2015–0116]

Agency Information Collection Request

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of submission of information collection request to Office of Management and Budget (OMB).

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments.

DATES: Comments must be submitted on or before August 4, 2016.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: NHTSA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Julie Kang, Ph.D., Contracting Officer's Technical Representative Task Order Manager, Human Factors/Engineering Integration Division, Office of Vehicle Crash Avoidance and Electronic Controls Research (NSR–310), National Highway Traffic Safety Administration, 1200 New Jersey Ave. SE., Washington, DC 20590. Dr. Kang's phone number is 202–366–5677. Her email address is *julie.kang@dot.gov.*

SUPPLEMENTARY INFORMATION: A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on January 4, 2016 (81 FR 141–142).

Title: Recruitment and Debriefing of Human Subjects for Head-Up Displays and Distraction Potential.

OMB Control Number: None.

Type of Request: New Information Collection.

Abstract: The National Highway Traffic Safety Administration's (NHTSA) mission is to save lives, prevent injuries, and reduce economic losses resulting from motor vehicle crashes. Head-up display (HUD) technology presents many opportunities and challenges for mitigating driver distraction, improving driver comfort, and engaging drivers with their vehicles. On one hand, the reduction of the distance that the eyes need to travel between a focal point on the forward road and a focal point on an in-vehicle display can minimize the amount of time required to view a display relative to a traditional Head-Down Display (HDD). There is also an added benefit in that peripheral roadway information can be processed while viewing a HUD, allowing partial support of some aspects of vehicle control, like lane keeping. On the other hand, humans have difficulty simultaneously processing two visual displays overlaid on each other. Viewing HUDs while driving may therefore prevent drivers from perceiving events in the environment, particularly centrally located hazards such as a braking lead vehicle. There is a concern that if drivers perceive HUDs to be safer than HDDs that they may not regulate the length of time they spend looking at the HUD. The HUD may therefore negatively alter drivers' visual scanning behavior. The benefits and drawbacks of using a HUD in a vehicle must therefore be fully investigated and properly understood.

The proposed study will examine the distraction potential of HUD use on driving performance. The information collection involves collecting eligibility information and demographic information. The study focuses on HUD technologies that display information about the state of the vehicle (*e.g.,* vehicle speed, navigation information) near the driver's forward field of view (*e.g.,* projected into the lower portion of the windshield in front of the driver).

Affected Public: Voluntary study participants.

Number of Respondents: VTTI will contact approximately 100 individuals by phone and use an eligibility questionnaire to determine their eligibility for the study. It is estimated that 60 of these individuals will qualify to be enrolled into the study. The 60 individuals who will be contacted are persons who have volunteered to take part in driving studies in the past. Businesses are ineligible for the sample and will not be contacted. These 60 individuals will complete an informed consent document and a demographic questionnaire.

Number of Responses: Completion of the eligibility questions is estimated to take approximately 10 minutes per individual (100 individuals). Information Sheet is expected to take 10 minutes per individual (60 individuals). Demographic questions are expected to take 3 minutes per individual (60 individuals). Informed consent is expected to take 5 minutes per individual (60 individuals).

Total Annual Burden Hours: 45 hours for all responses from all individuals.

Frequency of Collection: This is a one-time collection to obtain the target number of 48 valid test participants.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.95.

Nathaniel Beuse,

Associate Administrator, Office of Vehicle Safety Research.

[FR Doc. 2016–15635 Filed 7–1–16; 8:45 am]

BILLING CODE 4910–59–P

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Tuesday,
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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484
Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409 and 484

[CMS–1648–P]

RIN 0938–AS80

Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the Home Health Prospective Payment System (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor, effective for home health episodes of care ending on or after January 1, 2017. This proposed rule also: Implements the last year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates; updates the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking; implements the 2nd-year of a 3-year phase-in of a reduction to the national, standardized 60-day episode payment to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014; proposes changes to the methodology used to calculate outlier payments (with regards to payments made under the HH PPS for high-cost "outlier" episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care)); proposes changes in payment for Negative Pressure Wound Therapy (NPWT) performed using a disposable device for patient's under a home health plan of care; discusses our efforts to monitor the potential impacts of the rebasing adjustments mandated; includes an update on subsequent research and analysis as a result of the findings from the home health study; solicits comments on a potential process for grouping HH PPS claims centrally during claims processing; and proposes changes to the Home Health Value-Based Purchasing (HHVBP) Model, which was implemented on January 1, 2016; and proposes updates to the Home Health Quality Reporting Program (HH QRP).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 26, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1648–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1648–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1648–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For general information about the HH PPS, please send your inquiry via email to: *HomehealthPolicy@cms.hhs.gov.*

For information about the HHVBP Model, please send your inquiry via email to: *HHVBPquestions@cms.hhs.gov.*

Michelle Brazil, (410) 786–1648 for information about the HH quality reporting program.

Lori Teichman, (410) 786–6684, for information about HHCAHPS.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received at *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

In addition, because of the many terms to which we refer by abbreviation in this proposed rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ACH LOS	Acute Care Hospital Length of Stay
ADL	Activities of Daily Living
APU	Annual Payment Update
BBA	Balanced Budget Act of 1997, Pub. L. 105–33
BBRA	Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
CAD	Coronary Artery Disease
CAH	Critical Access Hospital
CBSA	Core-Based Statistical Area
CASPER	Certification and Survey Provider Enhanced Reports
CHF	Congestive Heart Failure
CMI	Case-Mix Index
CMP	Civil Money Penalty
CMS	Centers for Medicare & Medicaid Services
CoPs	Conditions of Participation
COPD	Chronic Obstructive Pulmonary Disease
CVD	Cardiovascular Disease
CY	Calendar Year
DM	Diabetes Mellitus
DRA	Deficit Reduction Act of 2005, Pub. L. 109–171, enacted February 8, 2006
FDL	Fixed Dollar Loss
FI	Fiscal Intermediaries
FISS	Fiscal Intermediary Shared System
FR	Federal Register
FY	Fiscal Year
HAVEN	Home Assessment Validation and Entry System
HCC	Hierarchical Condition Categories
HCIS	Health Care Information System
HH	Home Health
HHA	Home Health Agency
HHCAHPS	Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
HH PPS	Home Health Prospective Payment System
HHRG	Home Health Resource Group
HHVBP	Home Health Value-Based Purchasing
HIPPS	Health Insurance Prospective Payment System
HVBP	Hospital Value-Based Purchasing
ICD–9–CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM	International Classification of Diseases, Tenth Revision, Clinical Modification
IH	Inpatient Hospitalization
IMPACT	Act Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185)
IRF	Inpatient Rehabilitation Facility
LEF	Linear Exchange Function
LTCH	Long-Term Care Hospital
LUPA	Low-Utilization Payment Adjustment
MEPS	Medical Expenditures Panel Survey
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, enacted December 8, 2003
MSA	Metropolitan Statistical Area
MSS	Medical Social Services
NQF	National Quality Forum
NQS	National Quality Strategy
NRS	Non-Routine Supplies
OASIS	Outcome and Assessment Information Set
OBRA	Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–2–3, enacted December 22, 1987
OCESAA	Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. 105–277, enacted October 21, 1998
OES	Occupational Employment Statistics
OIG	Office of Inspector General
OT	Occupational Therapy
OMB	Office of Management and Budget
MFP	Multifactor productivity
PAMA	Protecting Access to Medicare Act of 2014
PAC–PRD	Post-Acute Care Payment Reform Demonstration
PEP	Partial Episode Payment Adjustment
PT	Physical Therapy
PY	Performance Year
PRRB	Provider Reimbursement Review Board
QAP	Quality Assurance Plan
RAP	Request for Anticipated Payment
RF	Renal Failure
RFA	Regulatory Flexibility Act, Pub. L. 96–354
RHHIs	Regional Home Health Intermediaries

RIA Regulatory Impact Analysis
SAF Standard Analytic File
SLP Speech-Language Pathology
SN Skilled Nursing
SNF Skilled Nursing Facility
TPS Total Performance Score
UMRA Unfunded Mandates Reform Act of 1995
VBP Value-Based Purchasing

I. Executive Summary

A. Purpose

This proposed rule would update the payment rates for home health agencies (HHAs) for calendar year (CY) 2017, as required under section 1895(b) of the Social Security Act (the Act). This would reflect the final year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit rates, and the NRS conversion factor finalized in the CY 2014 HH PPS final rule (78 FR 72256), as required under section 3131(a) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the "Affordable Care Act").

This proposed rule would update the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act and includes a reduction to the national, standardized 60-day episode payment rate in CY 2017 of 0.97 percent, to account for case-mix growth unrelated to increases in patient acuity (nominal case-mix growth) between CY 2012 and CY 2014 under the authority of section 1895(b)(3)(B)(iv) of the Act. With regards to payments made under the HH PPS for high-cost "outlier" episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care), this rule proposes changes to the methodology used to calculate outlier payments under the authority of section 1895(b)(5) of the Act. Also, in accordance with section 1834(s)(1) of the Act, as amended by the Consolidated Appropriations Act of 2016 (Pub. L. 114–113), this rule proposes changes in payment for Negative Pressure Wound Therapy (NPWT) performed using a disposable device for patient's under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act. This proposed rule also discusses our efforts to monitor for potential impacts of the rebasing adjustments mandated by section 3131(a) of the Affordable Care Act, provides an update on subsequent research and analysis as a result of the findings from the home health study required by section 3131(d) of the Affordable Care Act, and provides and update and solicits comments on a process to group HH PPS claims centrally during claims processing. Additionally, this rule proposes changes to the HHVBP Model, in which Medicare-certified HHAs in certain states are required to participate as of January 1, 2016, under the authority of section 1115A of the Act; and proposes changes to the home health quality reporting program requirements under the authority of section 1895(b)(3)(B)(v)(II) of the Act.

B. Summary of the Major Provisions

As required by section 3131(a) of the Affordable Care Act, and finalized in the CY 2014 HH PPS final rule (78 FR 77256, December 2, 2013), we are implementing the final year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor in section III.C.3. The rebasing adjustments for CY 2017 will reduce the national, standardized 60-day episode payment amount by $80.95, increase the national per-visit payment amounts by 3.5 percent of the national per-visit payment amounts in CY 2010 with the increases ranging from $1.79 for home health aide services to $6.34 for medical social services, and reduce the NRS conversion factor by 2.82 percent. In addition, in section III.C.3 of this rule, we are implementing a reduction to the national, standardized 60-day episode payment rate in CY 2017 of 0.97 percent to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. This reduction was finalized in the CY 2016 HH PPS final rule (80 FR 68624). Section III.A of this proposed rule discusses our efforts to monitor for potential impacts due to the rebasing adjustments mandated by section 3131(a) of the Affordable Care Act.

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with more current data. In section III.B.1 of this rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner. In section III.C.1 of this rule, we propose to update the payment rates under the HH PPS by the home health payment update percentage of 2.3 percent (using the 2010-based Home Health Agency (HHA) market basket update of 2.8 percent, minus 0.5 percentage point for productivity), as required by section 1895(b)(3)(B)(vi)(I) of the Act, and in section III.C.2 of this rule, we propose to update the CY 2017 home health wage index using more current hospital wage data. In section III.D, we are proposing to revise the current methodology used to estimate the cost of an episode of care to determine whether the episode of care would receive an outlier payment. The methodology change includes calculating the cost of an episode of care using a cost-per-unit calculation, which takes into account visit length, rather than the current methodology that uses a cost-per-visit calculation. In section III.E of this proposed rule, as a result of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113), we are proposing changes in payment for when Negative Pressure Wound Therapy (NPWT) is performed using a disposable device for a patient under a home health plan of care and for which payment is otherwise made under the HH PPS. In section III.F of this rule, we provide an update on our recent research and analysis pertaining to the home health study required by section 3131(d) of the Affordable Care Act. Finally, in section III.G of this proposed rule, we provide an update and solicit comments on a process for grouping the HH PPS claims centrally during claims processing.

In section IV of this rule, we are proposing the following changes to the HHVBP Model implemented January 1, 2016. We propose to remove the definition for "starter set"; propose to revise the definition for "benchmark"; propose to calculate benchmarks and achievement thresholds at the state level; propose a minimum requirement of eight HHAs in a cohort; propose to increase the time frame for submitting New Measure data; propose to remove four measures from the set of applicable measures; propose to adjust the reporting period and submission date for one of the New Measures; propose to add an appeals process that includes the existing recalculation process; and we are providing an update on the progress towards developing public reporting of performance under the HHVBP Model.

This proposed rule also proposes updates to the Home Health Quality Reporting Program in section V, including the adoption of four new quality measures, the removal of a number of measures, data submission requirements, and data review and correction policies.

C. Summary of Costs and Transfers

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

Provision description	Costs	Transfers
CY 2017 HH PPS Payment Rate Update	....	The overall economic impact of the HH PPS payment rate update is an estimated −$180 million (−1.0 percent) in payments to HHAs.
CY 2017 HHVBP Model	....	The overall economic impact of the HHVBP Model provision for CY 2018 through 2022 is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases to the HHAs competing in the model.

II. Background

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare HH services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered HH services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled "Prospective Payment For Home Health Services." Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount, to include all costs for HH services covered and paid for on a reasonable cost basis, and that such amounts be initially based on the most recent audited cost report data available to the Secretary; and (2) the standardized prospective payment amount is to be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act requires an annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels, respectively. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for HH services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) for Fiscal Year 1999, (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999, (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for HH services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of HH services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the HH market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes set out in section 3131 of the Affordable Care Act was an amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016. Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) amended section 421(a) of the MMA to extend the rural add-on for 2 more years. Section 421(a) of the MMA, as amended by section 210 of the MACRA, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2018.

Section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185, enacted on Oct. 6, 2014) amended Title XVIII of the Act, in part, by adding a new section 1899B, which imposes new data reporting requirements for certain post-acute care (PAC) providers, including HHAs. Under section 1899B(a)(1) of the Act, certain post-acute care (PAC) providers (defined in section 1899B(a)(2)(A) of the Act as HHAs, SNFs, IRFs, and LTCHs) must submit standardized patient assessment data in accordance with section 1899B(b) of the Act, data on quality measures required under section 1899B(c)(1) of the Act, and data on resource use, and other measures required under section 1899B(d)(1) of the Act. The Act also requires the Secretary to specify these measures insofar as they are respect to certain domains no later than the applicable specified application date that applies to each domain. The specific specified application dates that apply to each PAC provider type and domain are described in section 1899B(a)(2)(E) of the Act.

B. System for Payment of Home Health Services

Generally, Medicare makes payment under the HH PPS on the basis of a national standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national standardized 60-day episode rate includes the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is no longer part of the national standardized 60-day episode rate and is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor (See section II.D.4.e). Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

C. Updates to the Home Health Prospective Payment System

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the HH PPS for CY 2008. The CY 2008 HH PPS final rule included an analysis performed on CY 2005 HH claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. Case-mix represents the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 2005 case-mix data to evaluate if any portion of the 12.78 percent increase was associated with a change in the actual clinical condition of HH patients. We examined data on demographics, family severity, and non-HH Part A Medicare expenditures to predict the average case-mix weight for 2005. We identified 8.03 percent of the total case-mix change as real, and therefore, decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent (0.1278 * (1 − 0.0803) = 0.1175).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented a 1.32 percent reduction to the payment rates for CY 2013 to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010 (0.2390 * (1 − 0.1597) = 0.2008). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532).

Section 3131(a) of the Affordable Care Act also required that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we were required to phase in any adjustment over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specified that the maximum rebasing adjustment was to be no more than 3.5 percent per year of the CY 2010 rates. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of $80.95 per year, increases to the national per-visit payment rates per year as reflected in Table 2, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper. In the CY 2015 HH PPS final rule (79 FR 66032), we implemented the 2nd year of the 4 year phase-in of the rebasing adjustments to the HH PPS payment rates and made changes to the HH PPS case-mix weights. In addition, we simplified the face-to-face encounter regulatory requirements and the therapy reassessment timeframes.

TABLE 2—MAXIMUM ADJUSTMENTS TO THE NATIONAL PER-VISIT PAYMENT RATES

[Not to exceed 3.5 percent of the amount(s) in CY 2010]

	2010 National per-visit payment rates	Maximum adjustments per year (CY 2014 through CY 2017)
Skilled Nursing	$113.01	$3.96
Home Health Aide	51.18	1.79
Physical Therapy	123.57	4.32
Occupational Therapy	124.40	4.35
Speech-Language Pathology	134.27	4.70
Medical Social Services	181.16	6.34

In the CY 2016 HH PPS final rule (80 FR 68624), we implemented the 3rd year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined above).

In the CY 2016 HH PPS final rule, we also recalibrated the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget neutral manner, and finalized reductions to the national, standardized 60-day episode payment rate in CY 2016, CY 2017, and CY 2018 of 0.97 percent in each year to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. Finally, we continued to apply the payment increase of 3 percent for HH services provided in rural areas (as defined in section 1886(d)(2)(D) of the Act) to episodes or visits ending before January 1, 2018.

III. Proposed Provisions of the Home Health Prospective Payment System

A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments

1. Analysis of FY 2014 HHA Cost Report Data

As part of our efforts in monitoring the potential impacts of the rebasing adjustments finalized in the CY 2014 HH PPS final rule (78 FR 72293), we continue to update our analysis of home health cost report and claims data. In the CY 2014 HH PPS final rule, using 2011 cost report and 2012 claims data, we estimated the 2013 60-day episode cost to be $2,565.51 (78 FR 72277). In that final rule, we stated that our analysis of 2011 cost report data and 2012 claims data indicated a need for a −3.45 percent rebasing adjustment to the national, standardized 60-day episode payment rate each year for 4 years. However, as specified by statute, the rebasing adjustment is limited to 3.5 percent of the CY 2010 national, standardized 60-day episode payment rate of $2,312.94 (74 FR 58106), or $80.95. We stated that given that a −3.45 percent adjustment for CY 2014 through CY 2017 would result in larger dollar amount reductions than the maximum dollar amount allowed under section 3131(a) of the Affordable Care Act of $80.95, we were limited to implementing a reduction of $80.95 (approximately 2.8 percent of the standardized payment amount for CY 2014) to the national, standardized 60-day episode payment amount each year for CY 2014 through CY 2017.

In the CY 2015 HH PPS final rule, (79 FR 66032–66118) using 2012 cost report and 2013 claims data, we estimated the 2013 60-day episode cost to be $2,485.24 (79 FR 66037). Similar to our discussion in the CY 2014 HH PPS final rule, we stated that absent the Affordable Care Act's limit to rebasing, in order to align payments with costs, a −4.21 percent adjustment would have been applied to the national, standardized 60-day episode payment amount each year for CY 2014 through CY 2017.

In the CY 2016 HH PPS proposed rule (80 FR 39846–39866), using 2013 cost report and 2013 claims data, we estimated the 2013 60-day episode cost to be $2,402.11 (80 FR 39846). Similar to our discussion in the CY 2014 HH PPS final rule and the CY 2015 HH PPS final rule, we stated that absent the Affordable Care Act's limit to rebasing, in order to align payments with costs, a −5.02 percent adjustment would have been applied to the national, standardized 60-day episode payment amount each year for CY 2014 through CY 2017.

For this proposed rule, we analyzed 2014 HHA cost report data and 2014 HHA claims data to determine whether the average cost per episode was higher using 2014 cost report data compared to the 2011 cost report and 2012 claims da006used in calculating the rebasing adjustments. To determine the 2014 average cost per visit per discipline, we applied the same trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) and weighted the costs per visit from the 2014 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative according to 2014 claims data. The 2014 average number of visits was taken from 2014 claims data. We estimate the cost of a 60-day episode in CY 2014 to be $2,373.87 using 2014 cost report data (Table 3). Our latest analysis of 2014 cost report and 2014 claims data suggests that an even larger reduction (−5.30 percent) than the reduction described in the CY 2014 HH PPS final rule (−3.45 percent) or the reductions described in the CY 2015 HH PPS final rule and the CY 2016 HH PPS proposed rule (−4.21 and −5.02 percent, respectively) would have been needed in order to align payments with costs. The decrease in the estimated 60-day episode cost from $2,402.11 in CY 2013 to $2,373.87 in CY 2014 was due to both a lower average cost per visit for skilled nursing and home health aide services in 2014 compared to 2013 and lower average number of visits for skilled nursing and home health aide services per episode in 2014 compared to 2013.

TABLE 3—2014 ESTIMATED COST PER EPISODE

Discipline	2014 Average costs per visit	2014 Average number of visits	2014 60-Day episode costs
Skilled Nursing	$128.68	9.09	$1,169.70
Home Health Aide	56.59	2.19	123.93
Physical Therapy	155.90	5.18	807.56
Occupational Therapy	153.69	1.30	199.80
Speech-Language Pathology	166.98	0.26	43.41
Medical Social Services	210.48	0.14	29.47
Total	....	18.16	2,373.87

Source: FY 2014 Medicare cost report data and 2014 Medicare claims data from the standard analytic file (as of June 30, 2015) for episodes (excluding low-utilization payment adjusted episodes and partial-episode-payment adjusted episodes) ending on or before December 31, 2014 for which we could link an OASIS assessment.

2. Analysis of CY 2015 HHA Claims Data

In the CY 2014 HH PPS final rule (78 FR 72256), some commenters expressed concern that the rebasing of the HH PPS payment rates would result in HHA closures and would therefore diminish access to home health services. In addition to examining more recent cost report data, for this proposed rule we examined home health claims data from the first 2 years (CY 2014 and CY 2015) of the 4-year phase-in of the rebasing adjustments (CY 2014 through CY 2017), the first calendar year of the HH PPS (CY 2001), and claims data for the 3 years before implementation of the rebasing adjustments (CY 2011–2013). Preliminary analysis of CY 2015 home health claims data indicates that the number of episodes decreased by 3.8 percent from 2013 to 2014, and decreased by 1.7 percent from 2014 to 2015. In addition, the number of home health users that received at least one episode of care decreased by 2.95 percent between 2013 and 2014, and decreased slightly by 0.5 percent from 2014 to 2015.The number of FFS beneficiaries has remained the relatively constant between 2013 and 2015. Between 2013 and 2014 there appears to be a net decrease in the number of HHAs billing Medicare for home health services of 1.6 percent, and a continued decrease of 2.7 percent from 2014 to 2015. We note that in CY 2015 there were 2.9 HHAs per 10,000 FFS beneficiaries, which is still markedly higher than the 1.9 HHAs per 10,000 FFS beneficiaries before the implementation of the HH PPS methodology in 2001. The number of home health users, as a percentage of FFS beneficiaries, has been decreasing since 2011, from 9.2 percent to 8.7 percent in 2015. We would note that preliminary FFS data on per-enrollee hospital and skilled nursing facility discharges and days indicates that there was a decrease in hospital discharges of approximately 0.7 percent and a decrease in SNF days of approximately 0.9 percent in CY 2015. Any decreases in hospital discharges and skilled nursing facility days could, in turn, impact home health utilization as those settings serve as important sources of home health referrals.

TABLE 4—HOME HEALTH STATISTICS, CY 2001 AND CY 2011 THROUGH CY 2015

	2001	2011	2012	2013	2014	2015
Number of episodes	3,896,502	6,821,459	6,727,875	6,708,923	6,451,283	6,340,932
Beneficiaries receiving at least 1 episode (Home Health Users)	2,412,318	3,449,231	3,446,122	3,484,579	3,381,635	3,365,512
Part A and/or B FFS beneficiaries	34,899,167	37,686,526	38,224,640	38,505,609	38,506,534	38,592,533
Episodes per Part A and/or B FFS beneficiaries	0.11	0.18	0.18	0.17	0.17	0.16
Home health users as a percentage of Part A and/or B FFS beneficiaries	6.9%	9.2%	9.0%	9.0%	8.8%	8.7%
HHAs providing at least 1 episode	6,511	11,446	11,746	11,889	11,693	11,381
HHAs per 10,000 Part A and/or B FFS beneficiaries	1.9	3.0	3.1	3.1	3.0	2.9

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on May 14, 2014 and August 19, 2014 for CY 2011, CY 2012, and CY 2013 data; accessed on May 7, 2015 for CY 2001 and CY 2014 data, and accessed on April 7, 2016 for CY 2015 data Medicare enrollment information obtained from the CCW Master Beneficiary Summary File. Beneficiaries are the total number of beneficiaries in a given year with at least 1 month of Part A and/or Part B Fee-for-Service coverage without having any months of Medicare Advantage coverage.

Note(s): These results include all episode types (Normal, PEP, Outlier, LUPA) and also include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim—first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

In addition to examining home health claims data from the first 2 years of the implementation of rebasing adjustments required by the Affordable Care Act and comparing utilization in those years (CY 2014 & CY 2015) to the 3 years prior to and to the first calendar year following the implementation of the HH PPS (CY 2001), we subsequently examined trends in home health utilization for all years starting in CY 2001 and up through CY 2015. Figure 1, displays the average number of visits per 60-day episode of care and the average payment per visit. While the average payment per visit has steadily increased from approximately $116 in CY 2001 to $166 for CY 2015, the average total number of visits per 60-day episode of care has declined, most notably between CY 2009 (21.7 visits per episode) and CY 2010 (19.8 visits per episode), which was the first year that the 10 percent agency-level cap on HHA outlier payments was implemented. As noted in section II.C, we also implemented a series of reductions to the national, standardized 60-day episode payment rate to account for increases in nominal case-mix, starting in CY 2008. The reductions to the 60-day episode rate were: 2.75 percent each year for CY 2008, CY 2009, and CY 2010; 3.79 percent for CY 2011 and CY 2012; and a 1.32 percent payment reduction for CY 2013. Figure 2 displays the average number of visits by discipline type for a 60-day episode of care and shows that while the number of therapy visits per 60-day episode of care has increased steadily, the number of skilled nursing and home health aide visits have decreased, between CY 2009 and CY 2015. Section III.F describes the results of the home health study required by section 3131(d) of the Affordable Care Act, which suggests that the current home health payment system may discourage HHAs from serving patients with clinically complex and/or poorly controlled chronic conditions who do not qualify for therapy but require a large number of skilled nursing visits. The home health study results seem to be consistent with the recent trend in the decreased number of visits per episode of care driven by decreases in skilled nursing and home health aide services evident in Figures 1 and 2.

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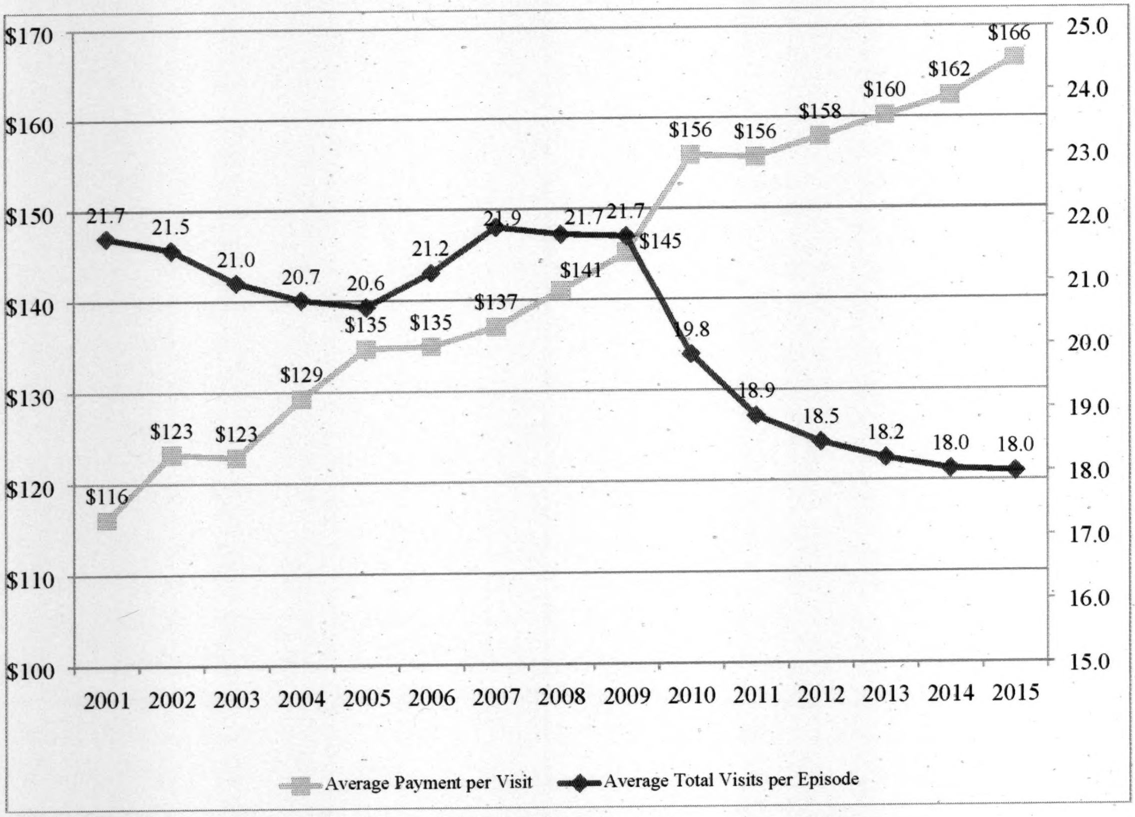
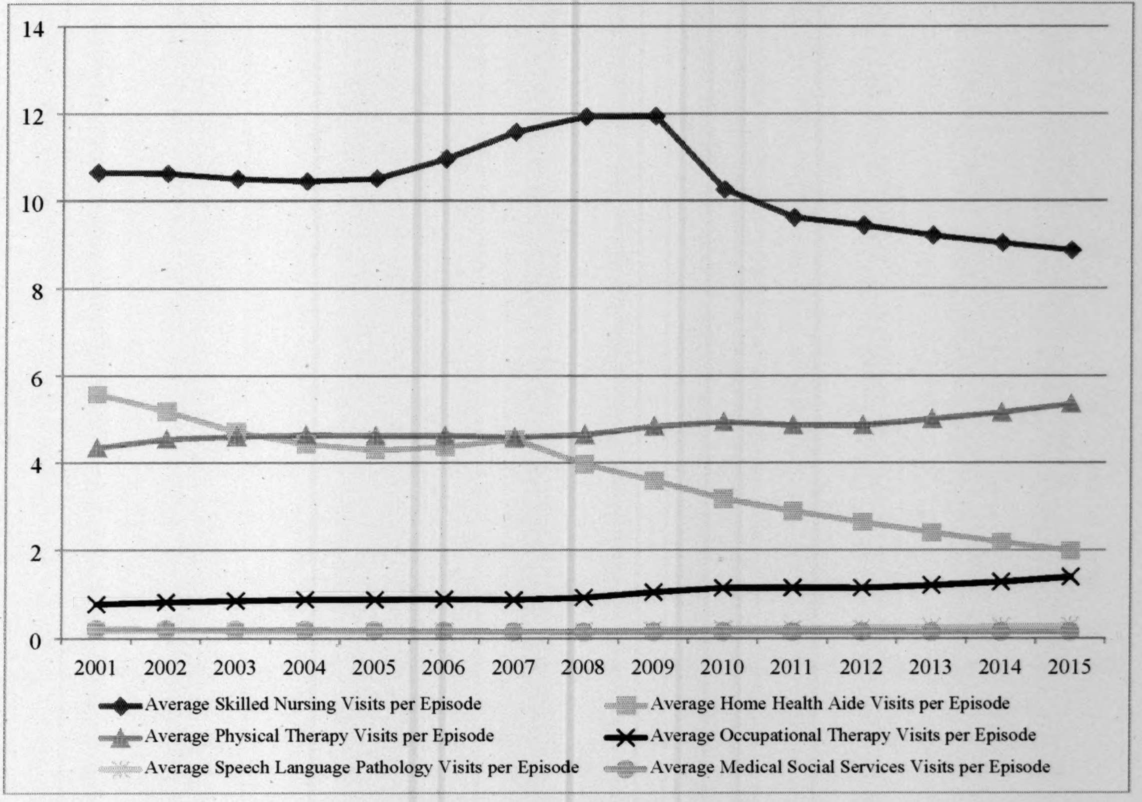
Figure 1: Average Total Number of Visits and Average Payment per Visit for a Medicare Home Health 60-Day Episode of Care, CY 2001 through CY 2015



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) – 2001 to 2014 data accessed on May 21, 2014, CY2015 data accessed on April 25, 2016.

Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

Figure 2: Average Number of Visits by Discipline Type for a Medicare Home Health 60-Day Episode of Care, CY 2001 through CY 2015



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) -- 2001 to 2014 data accessed on May 21, 2014, CY2015 data accessed on April 25, 2016.

Note(s): These results exclude LUPA episodes, but include episodes from outlying areas (outside of 50 States and District of Columbia). Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded. If a beneficiary is treated by providers from multiple states within a year the beneficiary is counted within each state's unique number of beneficiaries served.

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As part of our monitoring efforts, we also examined the trends in episode timing and service use over time. Currently, the first two 60-day episodes of care are considered ''early'' and third or later 60-day episodes of care are considered ''late'', as long as there is no more than a 60-day gap in care between one episode and the next. Specifically, we examined the percentage of early episodes with 0 to 19 therapy visits, late episodes with 0 to 19 therapy visits, and episodes with 20+ therapy visits from CY 2008 to CY 2015. In CY 2008, we implemented refinements to the HH PPS case-mix system. As part of those refinements, we added additional therapy thresholds and differentiated between early and late episodes for those episodes with less than 20+ therapy visits. Table 5 shows that the percentage of early and late episodes from CY 2008 to CY 2015 has remained relatively stable over time. There has been a slight decrease in the percentage of early episodes with 0 to 19 therapy visits from 65.9 percent in CY 2008 to 59.8 percent in CY 2015 and a slight increase in the percentage of late episodes with 0 to 19 therapy visits from 29.5 percent in CY 2008 to 33.5 percent in CY 2015. From CY 2014 to CY 2015, there was a slight decrease in the percentage of early and late episodes with 0 to 19 therapy visits and there was a slight increase in the percentage of episodes with 20+ therapy visits. In 2015, the case-mix weights for the third and later episodes of care with 0 to 19 therapy visits decreased as a result of the CY 2015 recalibration of the case-mix weights. Despite the decreases in the case-mix weights for the later episodes, the percentage of later episodes with 0 to 19 therapy visits did not change substantially.

Table 5—Home Health Episodes by Episode Timing, CY 2008 Through CY 2015

Year	All episodes	Number of early episodes (excluding episodes with 20+ visits)	% of early episodes (excluding episodes with 20+ visits)	Number of late episodes (excluding episodes with 20+ visits)	% of late episodes (excluding episodes with 20+ visits)	Number of episodes with 20+ visits	% of episodes with 20+ visits
2008	5,423,037	3,571,619	65.9	1,600,587	29.5	250,831	4.6
2009	6,530,200	3,701,652	56.7	2,456,308	37.6	372,240	5.7
2010	6,877,598	3,872,504	56.3	2,586,493	37.6	418,601	6.1
2011	6,857,885	3,912,982	57.1	2,564,859	37.4	380,044	5.5
2012	6,767,576	3,955,207	58.4	2,458,734	36.3	353,635	5.2
2013	6,733,146	4,023,486	59.8	2,347,420	34.9	362,240	5.4
2014	6,616,875	3,980,151	60.2	2,263,638	34.2	373,086	5.6
2015	6,340,931	3,789,676	59.8	2,123,485	33.5	427,770	6.7

Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW)—Accessed on April 7, 2016.

Note(s): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim—first claim") are excluded.

We also examined trends in admission source for home health episodes over time. Specifically, we examined the admission source for the "first or only" episodes of care (first episodes in a sequence of adjacent episodes of care or the only episode of care) from CY 2008 through CY 2015 (Figure 3). The percentage of first or only episodes with an acute admission source, defined as episodes with an inpatient hospital stay within the 14 days prior to a home health episode, has decreased from 38.6 percent in CY 2008 to 33.9 percent in CY 2015. The percentage of first or only episodes with a post-acute admission source, defined as episodes which had a stay at a skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long term care hospital (LTCH) within 14 days prior to the home health episode, slightly increased from 16.5 percent in CY 2008 to 18.1 percent in CY 2015. The percentage of first or only episodes with a community admission source, defined as episodes which did not have an acute or post-acute stay in the 14 days prior to the home health episode, increased from 37.4 percent in CY 2008 to 41.9 percent in CY 2015. Our findings on the trends in admission source are consistent to MedPAC's as outlined in their 2015 Report to the Congress.[1] However, MedPAC examined admission source trends from 2002 up through 2013 and concluded that "there has been tremendous growth in the use of home health for patients residing in the community, episodes not preceded by a prior hospitalization. The high rates of volume growth for these types of episodes, which have more than doubled since 2001, suggest there is significant potential for overuse, particularly since Medicare does not currently require any cost sharing for home health care."

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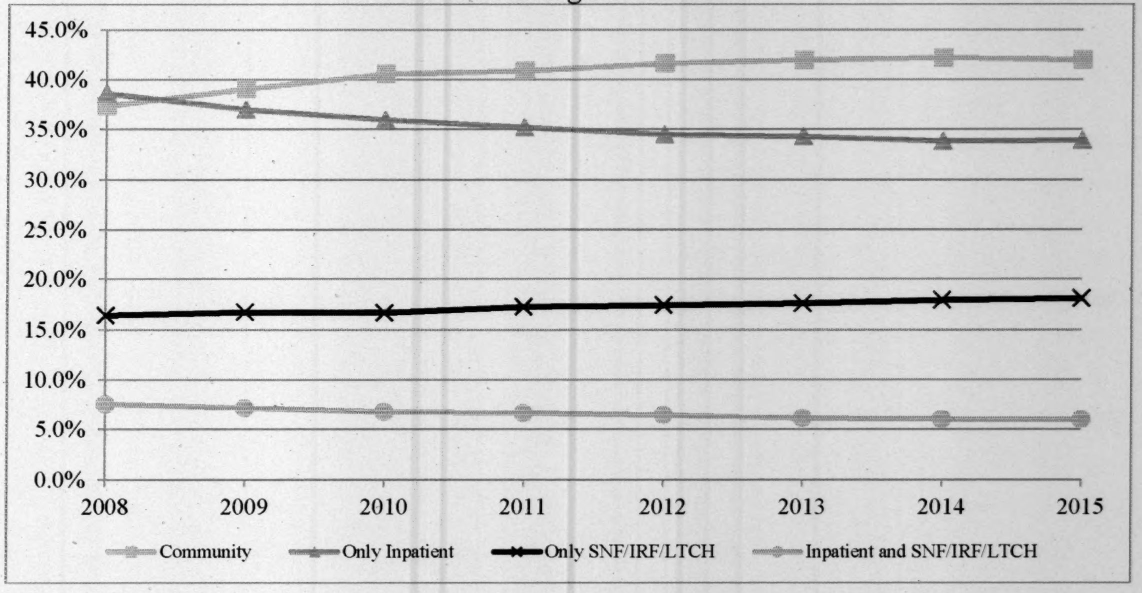
[1] Medicare Payment Advisory Commission (MedPAC), "Report to the Congress: Medicare Payment Policy". March 2015. P. 214. Washington, DC. Accessed on 4/21/2016 at *http://medpac.gov/documents/reports/march-2015-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0.*

Figure 3: Home Health Episode Trends by Admission Source (First or Only Episodes), CY 2008 through CY 2015



Source: National claims history (NCH) data obtained from Chronic Condition Warehouse (CCW) - Accessed on April 7, 2016.

Note(s): Only episodes with a through date in the year specified are included. Episodes with a claim frequency code equal to "0" ("Non-payment/zero claims") and "2" ("Interim - first claim") are excluded.

We will continue to monitor for potential impacts due to the rebasing adjustments required by section 3131(a) of the Affordable Care Act and other policy changes in the future. Independent effects of any one policy may be difficult to discern in years where multiple policy changes occur in any given year.

B. Proposed CY 2017 HH PPS Case-Mix Weights

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized a policy to annually recalibrate the HH PPS case-mix weights—adjusting the weights relative to one another—using the most current, complete data available. To recalibrate the HH PPS case-mix weights for CY 2017, we will use the same methodology finalized in the CY 2008 HH PPS final rule (72 FR 49762), the CY 2012 HH PPS final rule (76 FR 68526), and the CY 2015 HH PPS final rule (79 FR 66032). Annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns.

To generate the proposed CY 2017 HH PPS case-mix weights, we used CY 2015 home health claims data (as of December 31, 2015) with linked OASIS data. These data are the most current and complete data available at this time. We will use CY 2015 home health claims data (as of June 30, 2016) with linked OASIS data to generate the CY 2017 HH PPS case-mix weights in the CY 2017 HH PPS final rule. The process we used to calculate the HH PPS case-mix weights are outlined below.

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the CY 2014 Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim. The points for each of the variables for each leg of the model, updated with CY 2015 home health claims data, are shown in Table 6. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added together to determine an episode's functional score.

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TABLE 6: Case-Mix Adjustment Variables and Scores

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
	CLINICAL DIMENSION				
1	Primary or Other Diagnosis = Blindness/Low Vision				
2	Primary or Other Diagnosis = Blood disorders				
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms		5		5
4	Primary Diagnosis = Diabetes		3		2
5	Other Diagnosis = Diabetes				
6	Primary or Other Diagnosis = Dysphagia ***AND*** Primary or Other Diagnosis = Neuro 3 – Stroke	2	18		12
7	Primary or Other Diagnosis = Dysphagia ***AND*** M1030 (Therapy at home) = 3 (Enteral)	1	3		
8	Primary or Other Diagnosis = Gastrointestinal disorders				
9	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** M1630 (ostomy)= 1 or 2		5		
10	Primary or Other Diagnosis = Gastrointestinal disorders ***AND*** Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis, ***OR*** Neuro 2 - Peripheral neurological disorders, ***OR*** Neuro 3 - Stroke, ***OR*** Neuro 4 - Multiple Sclerosis				
11	Primary or Other Diagnosis = Heart Disease OR Hypertension				
12	Primary Diagnosis = Neuro 1 - Brain disorders and paralysis	3	12	7	9
13	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***AND*** M1840 (Toilet transfer) = 2 or more		4		4
14	Primary or Other Diagnosis = Neuro 1 - Brain disorders and paralysis ***OR*** Neuro 2 - Peripheral neurological disorders ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3				
15	Primary or Other Diagnosis = Neuro 3 - Stroke	2	10	1	3
16	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3				
17	Primary or Other Diagnosis = Neuro 3 - Stroke ***AND*** M1860 (Ambulation) = 4 or more				

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
18	Primary or Other Diagnosis = Neuro 4 - Multiple Sclerosis ***AND AT LEAST ONE OF THE FOLLOWING:*** M1830 (Bathing) = 2 or more ***OR*** M1840 (Toilet transfer) = 2 or more ***OR*** M1850 (Transferring) = 2 or more ***OR*** M1860 (Ambulation) = 4 or more		8		
19	Primary or Other Diagnosis = Ortho 1 - Leg Disorders or Gait Disorders ***AND*** M1324 (most problematic pressure ulcer stage)= 1, 2, 3 or 4	7		7	
20	Primary or Other Diagnosis = Ortho 1 - Leg OR Ortho 2 - Other orthopedic disorders ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	2		2	
21	Primary or Other Diagnosis = Psych 1 – Affective and other psychoses, depression	2	4		2
22	Primary or Other Diagnosis = Psych 2 - Degenerative and other organic psychiatric disorders	1	1		
23	Primary or Other Diagnosis = Pulmonary disorders	1			3
24	Primary or Other Diagnosis = Pulmonary disorders ***AND*** M1860 (Ambulation) = 1 or more		3		
25	Primary Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications	5	19	5	11
26	Other Diagnosis = Skin 1 - Traumatic wounds, burns, post-operative complications	5	9	5	9
27	Primary or Other Diagnosis = Skin 1 -Traumatic wounds, burns, and post-operative complications ***OR*** Skin 2 – Ulcers and other skin conditions ***AND*** M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	2			
28	Primary or Other Diagnosis = Skin 2 - Ulcers and other skin conditions	1	14	6	14
29	Primary or Other Diagnosis = Tracheostomy	3	15	3	15
30	Primary or Other Diagnosis = Urostomy/Cystostomy		18		13
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)	1	18	6	18
32	M1030 (Therapy at home) = 3 (Enteral)		19		12
33	M1200 (Vision) = 1 or more				

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0-13	14+	0-13	14+
	EQUATION:	*1*	*2*	*3*	*4*
34	M1242 (Pain)= 3 or 4	3		1	
35	M1308 = Two or more pressure ulcers at stage 3 or 4	6	10	6	10
36	M1324 (Most problematic pressure ulcer stage)= 1 or 2	4	20	7	16
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	9	31	11	25
38	M1334 (Stasis ulcer status)= 2	5	22	12	22
39	M1334 (Stasis ulcer status)= 3	8	23	14	23
40	M1342 (Surgical wound status)= 2	2	8	7	13
41	M1342 (Surgical wound status)= 3		6	7	12
42	M1400 (Dyspnea) = 2, 3, or 4				
43	M1620 (Bowel Incontinence) = 2 to 5		4		3
44	M1630 (Ostomy)= 1 or 2	4	12	2	8
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3				
FUNCTIONAL DIMENSION					
46	M1810 or M1820 (Dressing upper or lower body)= 1, 2, or 3	1		1	
47	M1830 (Bathing) = 2 or more	6	6	5	2
48	M1840 (Toilet transferring) = 2 or more	1	3		1
49	M1850 (Transferring) = 2 or more	3		2	
50	M1860 (Ambulation) = 1, 2 or 3	7		4	
51	M1860 (Ambulation) = 4 or more	8	10	7	9

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of December 31, 2015) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Note(s): Points are additive; however, points may not be given for the same line item in the table more than once.

Please see Medicare Home Health Diagnosis Coding guidance at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.html for definitions of primary and secondary diagnoses.

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In updating the four-equation model for CY 2017, using 2015 home health claims data (the last update to the four-equation model for CY 2016 used CY 2014 home health claims data), there were few changes to the point values for the variables in the four-equation model. These relatively minor changes reflect the change in the relationship between the grouper variables and resource use between CY 2014 and CY 2015. The CY 2017 four-equation model resulted in 110 point-giving variables being used in the model (as compared to the 124 variables for the CY 2016 recalibration). There were ten variables that were added to the model and 24 variables that were dropped from the model due to the absence of additional resources associated with the variable. Of the variables that were in both the four-equation model for CY 2016 and the four-equation model for CY 2017, the points for 37 variables increased in the CY 2017 four-equation model and the points for 38 variables decreased in the CY 2017 4-equation model. There were 25 variables with the same point values.

Step 2: Re-defining the clinical and functional thresholds so they are reflective of the new points associated with the CY 2017 four-equation model. After estimating the points for each of the variables and summing the clinical and functional points for each episode, we look at the distribution of the clinical score and functional score, breaking the episodes into different steps. The categorizations for the steps are as follows:

- Step 1: First and second episodes, 0–13 therapy visits.
- Step 2.1: First and second episodes, 14–19 therapy visits.
- Step 2.2: Third episodes and beyond, 14–19 therapy visits.
- Step 3: Third episodes and beyond, 0–13 therapy visits.
- Step 4: Episodes with 20+ therapy visits.

We then divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.[2] Also, we looked at the average resource use associated with each clinical and functional score and used that as a guide for setting our thresholds. We grouped scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off of the CY 2017 four-equation model points are shown in Table 7.

TABLE 7—CY 2017 CLINICAL AND FUNCTIONAL THRESHOLDS

		1st and 2nd Episodes		3rd+ Episodes		All episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step:		1	2.1	3	2.2	4.
Equation(s) used to calculate points: (see Table 6).		1	2	3	4	(2&4).
Dimension	Severity level.					
Clinical	C1	0 to 1	0 to 1	0	0 to 1	0 to 3.
	C2	2 to 3	2 to 7	1	2 to 9	4 to 17.
	C3	4+	8+	2+	10+	18+.
Functional	F1	0 to 13	0 to 7	0 to 6	0	0 to 2.
	F2	14	8 to 13	7 to 10	1 to 11	3 to 6.
	F3	15+	14+	11+	12+	7+.

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model are indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 8 shows the regression coefficients for the variables in the payment regression model updated with CY 2015 home health claims data. The R-squared value for the payment regression model is 0.4919 (an increase from 0.4822 for the CY 2016 recalibration).

TABLE 8—PAYMENT REGRESSION MODEL

Variable description	New payment regression coefficients
Step 1, Clinical Score Medium	$25.75
Step 1, Clinical Score High	60.84
Step 1, Functional Score Medium	71.60
Step 1, Functional Score High	108.83
Step 2.1, Clinical Score Medium	53.35
Step 2.1, Clinical Score High	129.94
Step 2.1, Functional Score Medium	11.54
Step 2.1, Functional Score High	67.03
Step 2.2, Clinical Score Medium	33.94
Step 2.2, Clinical Score High	188.53
Step 2.2, Functional Score Medium	0.31
Step 2.2, Functional Score High	63.34
Step 3, Clinical Score Medium	9.35
Step 3, Clinical Score High	95.01
Step 3, Functional Score Medium	56.44
Step 3, Functional Score High	88.01
Step 4, Clinical Score Medium	76.63
Step 4, Clinical Score High	261.74
Step 4, Functional Score Medium	22.89
Step 4, Functional Score High	73.10
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	498.19
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	515.73
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	−73.96
Step 4, All Episodes, 20+ Therapy Visits	906.64
Intercept	393.43

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of December 31, 2015) for which we had a linked OASIS assessment.

Step 4: We use the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divide these predicted values by the mean of the dependent variable (that is, the average wage-weighted minutes of care across all episodes used in the payment regression). This division constructs the weight for each episode, which is simply the ratio of the episode's predicted wage-weighted minutes of care divided by the average wage-weighted minutes of care in the sample. Each episode is then aggregated into one of the 153 home health resource groups (HHRGs) and the "raw" weight for each HHRG was calculated as the average of the episode weights within the HHRG.

Step 5: The raw weights associated with 0 to 5 therapy visits are then increased by 3.75 percent, the weights associated with 14–15 therapy visits are decreased by 2.5 percent, and the weights associated with 20+ therapy visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.[3]

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[2] For Step 1, 62% of episodes were in the medium functional level (All with score 14).

For Step 2.1, 71.0% of episodes were in the low functional level (Most with score 6).

For Step 2.2, 83.2% of episodes were in the medium functional level (Most with score 2 or 3).

For Step 3, 51.3% of episodes were in the medium functional level (Most with score 10).

For Step 4, 54.4% of episodes were in the medium functional level (Most with score 6).

Step 6: After the adjustments in step 5 are applied to the raw weights, the weights are further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same clinical severity level, functional severity level, and early/later episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds are gradually increased. We do this by interpolating between the main thresholds on the model (from 0–5 to 14–15 therapy visits, and from 14–15 to 20+ therapy visits). We use a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0–5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7–9 therapy visits) are constant. This interpolation is identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.[4] This last step creates the proposed CY 2017 case-mix weights shown in Table 9.

TABLE 9—PROPOSED CY 2017 CASE-MIX PAYMENT WEIGHTS

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2017 weights
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5972
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.7322
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8671
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	1.0021
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1370
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.7059
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.8224
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9389
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0554
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1719
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7624
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8835
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	1.0045
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.1255
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2466
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.6363
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7787
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.9210
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0634
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.2057
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.7450
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8689
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9928
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.1167
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.2406
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.8015
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.9300
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	1.0584
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1868
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.3153
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6896
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.8431
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9967
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.1502
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3038
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7983
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.9334
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0685
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.2036
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3387
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.8548
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9944
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1341
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.2737
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4133

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[3] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy.* March 2011, P. 176.

[4] When computing the average, we compute a weighted average, assigning a value of one to each normal episode and a value equal to the episode length divided by 60 for PEPs.

TABLE 9—PROPOSED CY 2017 CASE-MIX PAYMENT WEIGHTS—Continued

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2017 weights
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2720
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4503
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6287
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2884
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4719
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6554
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3676
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5480
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7283
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3481
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.5366
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7251
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3645
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5582
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7518
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.4437
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6342
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8247
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4573
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6952
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9330
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4738
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7168
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9597
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5530
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7928
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0326
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2970
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4670
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6370
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2974
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4779
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6584
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3873
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5611
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7349
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3454
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.5348
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7242
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3458
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5457
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7455
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.4358
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6289
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8220
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.5659
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7676
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9692
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5664
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7785
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9906
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.6563
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8617
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0671
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4850
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6474
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8098
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9722
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1346
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5706
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.7160
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8614
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	1.0067
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1521
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6186
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7723
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9261
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0798

TABLE 9—PROPOSED CY 2017 CASE-MIX PAYMENT WEIGHTS—Continued

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3 = high)	Proposed CY 2017 weights
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2336
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4992
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6684
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8377
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	1.0069
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1761
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5848
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7370
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8892
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0414
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1936
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6328
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7934
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9540
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.1146
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2752
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6292
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.8165
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	1.0039
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1912
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3786
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7149
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8852
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0555
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.2258
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3961
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7628
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.9415
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1202
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2989
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4776
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.8071
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.8389
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.9087
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.9136
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.9454
40231	All Episodes, 20+ Therapy Visits	C2F3S1	2.0152
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.1709
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.2027
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.2725

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the proposed CY 2017 national, standardized 60-day episode payment rate (see section III.C.3. of this proposed rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2017 HH PPS case-mix weights (developed using CY 2015 home health claims data) are applied to CY 2015 utilization (claims) data to total payments when CY 2016 HH PPS case-mix weights (developed using CY 2014 home health claims data) are applied to CY 2015 utilization data. This produces a case-mix budget neutrality factor for CY 2017 of 1.0062, based on CY 2015 claims data as of December 31, 2015.

C. Proposed CY 2017 Home Health Payment Rate Update

1. Proposed CY 2017 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2017 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. The home health market basket was rebased and revised in CY 2013. A detailed description of how we derive the HHA market basket is available in the CY 2013 HH PPS final rule (77 FR 67080–67090).

Section 3401(e) of the Affordable Care Act, adding new section 1895(b)(3)(B)(vi) to the Act, requires that, in CY 2015 (and in subsequent calendar years), the market basket percentage under the HHA prospective payment system as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. The statute defines the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act, to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

Using IHS Global Insight's (IGI) first quarter 2016 forecast, the MFP adjustment for CY 2017 (the 10-year moving average of MFP for the period ending CY 2017) is projected to be 0.5 percent. Thus, in accordance with section 1895(b)(3)(B)(iii) of the Act, we propose to base the CY 2017 market basket update, which is used to determine the applicable percentage increase for the HH payments, on the most recent estimate of the proposed 2010-based HH market basket (currently estimated to be 2.8 percent based on IGI's first quarter 2016 forecast). We propose to then reduce this percentage increase by the current estimate of the MFP adjustment for CY 2017 of 0.5 percentage point (the 10-year moving average of MFP for the period ending CY 2017 based on IGI's first quarter 2016 forecast), in accordance with 1895(b)(3)(B)(vi). Therefore, the current estimate of the CY 2017 HH payment update is 2.3 percent (2.8 percent market basket update, less 0.5 percentage point MFP adjustment). Furthermore, we note that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data to determine the CY 2017 market basket update and MFP adjustment in the final rule.

Section 1895(b)(3)(B) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2017, the home health payment update would be 0.3 percent (2.3 percent minus 2 percentage points).

2. Proposed CY 2017 Home Health Wage Index

a. Background

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We propose to continue this practice for CY 2017, as we continue to believe that, in the absence of HH-specific wage data, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we propose to continue to use the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2017, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013 (FY 2013 cost report data). We would apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

b. Updates

Previously, we determined each HHA's labor market area based on definitions of metropolitan statistical areas (MSAs) issued by the Office of Management and Budget (OMB). In the CY 2006 HH PPS final rule (70 FR 68132), we adopted revised labor market area definitions as discussed in the OMB Bulletin No. 03–04 (June 6, 2003). This bulletin announced revised definitions for MSAs and the creation of micropolitan statistical areas and core-based statistical areas (CBSAs). The bulletin is available online at *www.whitehouse.gov/omb/bulletins/b03-04.html.*

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. This bulletin is available online at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* This bulletin states that it "provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data."

While the revisions OMB published on February 28, 2013 are not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2006, the February 28, 2013 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart.

In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we finalized changes to the HH PPS wage index based on the OMB delineations, as described in OMB Bulletin No. 13–01. In CY 2015, we included a one-year transition to those delineations by using a blended wage index for CY 2015.

The OMB's most recent update to the geographic area delineations was published on July 15, 2015 in OBM bulletin 15–01. This bulletin is available online at *https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15-01.pdf.* The revisions to the delineations that affect the HH PPS are changes to CBSA titles and the addition of CBSA 21420, Enid, Oklahoma. CBSA 21420 encompasses Garfield County, Oklahoma.

In order to address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2017 HH PPS wage index, we propose to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we would use the average wage index from all contiguous CBSAs as a reasonable proxy. For FY 2017, there are no rural geographic areas without hospitals for which we would apply this policy. For rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we would continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we would use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2017, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

The proposed CY 2017 wage index is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html*

3. Proposed CY 2017 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in 42 CFR 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode rate would continue to be 78.535 percent and the non-labor-related share would continue to be 21.465 percent as set out in the CY 2013 HH PPS final rule (77 FR 67068). The CY 2017 HH PPS rates would use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and would be adjusted as described in section III.C. of this rule. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode rate:

(1) Multiply the national 60-day episode rate by the patient's applicable case-mix weight.

(2) Divide the case-mix adjusted amount into a labor (78.535 percent) and a non-labor portion (21.465 percent).

(3) Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.

(4) Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

In accordance with section 1895(b)(3)(B) of the Act, this document constitutes the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus two percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare would use to pay the claim.

We may also adjust the 60-day case-mix and wage-adjusted episode payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in § 484.205(c) and § 484.230.
- A partial episode payment (PEP) adjustment as set forth in § 484.205(d) and § 484.235.
- An outlier payment as set forth in § 484.205(e) and § 484.240.

b. Proposed CY 2017 National, Standardized 60-Day Episode Payment Rate

Section 1895(3)(A)(i) of the Act required that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2017 national, standardized 60-day episode payment rate, we would apply a wage index standardization factor, a case-mix budget neutrality factor described in section III.B, a reduction of 0.97 percent to account for nominal case-mix growth from 2012 to 2014 as finalized in the CY 2016 HH PPS final rule (80 FR 68646), the rebasing adjustment described in section II.C, and the MFP-adjusted home health market basket update discussed in section III.C.1 of this proposed rule.

To calculate the wage index standardization factor, henceforth referred to as the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the proposed CY 2017 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2016 wage index. By dividing the total payments for non-LUPA episodes using the proposed CY 2017 wage index by the total payments for non-LUPA episodes using the CY 2016 wage index, we obtain a wage index budget neutrality factor of 0.9990. We would apply the wage index budget neutrality factor of 0.9990 to the proposed CY 2017 national, standardized 60-day episode rate.

As discussed in section III.B of this proposed rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we would apply a case-mix weight budget neutrality factor to the CY 2017 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2017 case-mix weights are applied to CY 2015 utilization (claims) data to total payments when CY 2016 case-mix weights are applied to CY 2015 utilization data. The case-mix budget neutrality factor for CY 2017 would be 1.0062 as described in section III.B.1 of this proposed rule.

Next, as discussed in the CY 2016 HH PPS final rule (80 FR 68646), we would apply a reduction of 0.97 percent to the national, standardized 60-day episode payment rate in CY 2017 to account for nominal case-mix growth between CY 2012 and CY 2014. Then, we would apply the −$80.95 rebasing adjustment finalized in the CY 2014 HH PPS final rule (78 FR 72256), and discussed in section II.C. Lastly, we would update the proposed payment rates by the proposed CY 2017 HH payment update percentage of 2.3 percent (MFP-adjusted home health market basket update) as described in section III.C.1 of this proposed rule. The proposed CY 2017 national, standardized 60-day episode payment rate is calculated in Table 10.

TABLE 10—PROPOSED CY 2017 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2016 National, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update	Proposed CY 2017 national, standardized 60-day episode payment
$2,965.12	× 0.9990	× 1.0062	× 0.9903	−$80.95	1.023	$2,936.68

The proposed CY 2017 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the proposed CY 2017 HH payment update (2.3 percent) minus 2 percentage points and is shown in Table 11.

TABLE 11—PROPOSED CY 2017 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2016 National, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update minus 2 percentage points	Proposed CY 2017 national, standardized 60-day episode payment
$2,965.12	× 0.9990	× 1.0062	× 0.9903	−$80.95	× 1.003	$2,879.27

c. Proposed CY 2017 National Per-Visit Rates

The national per-visit rates are used to pay LUPAs (episodes with four or fewer visits) and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide);
- Medical Social Services (MSS);
- Occupational therapy (OT);
- Physical therapy (PT);
- Skilled nursing (SN); and
- Speech-language pathology (SLP).

To calculate the proposed CY 2017 national per-visit rates, we start with the CY 2016 national per-visit rates. We then apply a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments and then we increase each of the six per-visit rates by the maximum rebasing adjustments described in section II.C. of this rule. We calculate the wage index budget neutrality factor by simulating total payments for LUPA episodes using the proposed CY 2017 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2016 wage index. By dividing the total payments for LUPA episodes using the proposed CY 2017 wage index by the total payments for LUPA episodes using the CY 2016 wage index, we obtain a wage index budget neutrality factor of 0.9998. We would apply the wage index budget neutrality factor of 0.9998 in order to calculate the CY 2017 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, there is no case-mix weights budget neutrality factor needed to ensure budget neutrality for LUPA payments. Finally, the per-visit rates for each discipline are updated by the proposed CY 2017 HH payment update percentage of 2.3 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The proposed CY 2017 national per-visit rates are shown in Tables 12 and 13.

TABLE 12: PROPOSED CY 2017 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2016 per-visit payment	Wage index budget neutrality factor	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update	Proposed CY 2017 per-visit payment
Home Health Aide	$60.87	× 0.9998	+ $1.79	× 1.023	$64.09
Medical Social Services	215.47	× 0.9998	+ 6.34	× 1.023	226.87
Occupational Therapy	147.95	× 0.9998	+ 4.35	× 1.023	155.77
Physical Therapy	146.95	× 0.9998	+ 4.32	× 1.023	154.72
Skilled Nursing	134.42	× 0.9998	+ 3.96	× 1.023	141.54
Speech Language Pathology	159.71	× 0.9998	+ 4.70	× 1.023	168.16

The proposed CY 2017 per-visit payment rates for an HHA that does not submit the required quality data are updated by the proposed CY 2017 HH payment update percentage (2.3 percent) minus 2 percentage points and is shown in Table 13.

TABLE 13—PROPOSED CY 2017 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline type	CY 2016 per-visit rates	Wage index budget neutrality factor	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update minus 2 percentage points	Proposed CY 2017 per-visit rates
Home Health Aide	$60.87	× 0.9998	+ $1.79	× 1.003	$62.84
Medical Social Services	215.47	× 0.9998	+ 6.34	× 1.003	222.43
Occupational Therapy	147.95	× 0.9998	+ 4.35	× 1.003	152.73
Physical Therapy	146.95	× 0.9998	+ 4.32	× 1.003	151.69
Skilled Nursing	134.42	× 0.9998	+ 3.96	× 1.003	138.77
Speech Language Pathology	159.71	× 0.9998	+ 4.70	× 1.003	164.87

d. Low-Utilization Payment Adjustment (LUPA) Add-On Factors

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule, we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP (78 FR 72306). We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit would be $261.16 (1.8451 multiplied by $141.54), subject to area wage adjustment.

e. Proposed CY 2017 Non-routine Medical Supply (NRS) Payment Rates

Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the proposed CY 2017 NRS conversion factor, we start with the CY 2016 NRS conversion factor ($52.71) and apply the −2.82 percent rebasing adjustment described in section II.C. of this rule (1−0.0282 = 0.9718). We then update the conversion factor by the proposed CY 2017 HH payment update percentage (2.3 percent). We do not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The proposed NRS conversion factor for CY 2017 is shown in Table 14.

TABLE 14—PROPOSED CY 2017 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2016 NRS conversion factor	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update	Proposed CY 2017 NRS conversion factor
$52.71	× 0.9718	× 1.023	$52.40

Using the CY 2015 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 15.

TABLE 15—PROPOSED CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts
1	0	0.2698	$14.14
2	1 to 14	0.9742	51.05
3	15 to 27	2.6712	139.97
4	28 to 48	3.9686	207.95
5	49 to 98	6.1198	320.68
6	99+	10.5254	551.53

For HHAs that do not submit the required quality data, we begin with the CY 2016 NRS conversion factor ($52.71) and apply the −2.82 percent rebasing adjustment discussed in section II.C of this proposed rule (1−0.0282 = 0.9718). We then update the NRS conversion factor by the proposed CY 2017 HH payment update percentage (2.3 percent) minus 2 percentage points. The proposed CY 2017 NRS conversion factor for HHAs that do not submit quality data is shown in Table 16.

TABLE 16—PROPOSED CY 2017 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2015 NRS Conversion factor	CY 2017 Rebasing adjustment	Proposed CY 2017 HH payment update percentage minus 2 percentage Points	Proposed CY 2017 NRS conversion factor
$52.71	× 0.9718	× 1.003	$51.38

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 17.

TABLE 17—PROPOSED CY 2017 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts
1	0	0.2698	$13.86
2	1 to 14	0.9742	50.05
3	15 to 27	2.6712	137.25
4	28 to 48	3.9686	203.91
5	49 to 98	6.1198	314.44
6	99+	10.5254	540.80

f. Rural Add-On

Section 421(a) of the MMA required, for HH services furnished in a rural areas (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent.

Section 5201 of the DRA amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006 and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Public Law 114–10) amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 421 of the MMA, as amended, waives budget neutrality related to this provision, as the statute specifically states that the Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Act applicable to HH services furnished during a period to offset the increase in payments resulting in the application of this section of the statute.

For CY 2017, home health payment rates for services provided to beneficiaries in areas that are defined as rural under the OMB delineations would be increased by 3 percent as mandated by section 210 of the MACRA. The 3 percent rural add-on is applied to the national, standardized 60-day episode payment rate, national per visit rates, and NRS conversion factor when HH services are provided in rural (non-CBSA) areas. Refer to Tables 18 through 21 for these payment rates.

TABLE 18—PROPOSED CY 2017 PAYMENT AMOUNTS FOR 60-DAY EPISODES FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
Proposed CY 2017 national, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural national, standardized 60-day episode payment rate	Proposed CY 2017 national, standardized 60-day episode payment rate	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural national, standardized 60-day episode payment rate
$2,936.68	× 1.03	$3,024.78	$2,879.27	× 1.03	$2,965.65

TABLE 19—PROPOSED CY 2017 PER-VISIT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

	For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
HH Discipline type	Proposed CY 2017 per-visit rate	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural per-visit rates	Proposed CY 2017 per-visit rate	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural per-visit rates
HH Aide	$64.09	× 1.03	$66.01	$62.84	× 1.03	$64.73
MSS	226.87	× 1.03	233.68	222.43	× 1.03	229.10
OT	155.77	× 1.03	160.44	152.73	× 1.03	157.31
PT	154.72	× 1.03	159.36	151.69	× 1.03	156.24
SN	141.54	× 1.03	145.79	138.77	× 1.03	142.93
SLP	168.16	× 1.03	173.20	164.87	× 1.03	169.82

TABLE 20—PROPOSED CY 2017 NRS CONVERSION FACTORS FOR SERVICES PROVIDED IN A RURAL AREA

For HHAs that DO submit quality data			For HHAs that DO NOT submit quality data		
Proposed CY 2017 conversion factor	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural NRS conversion factor	Proposed CY 2017 conversion factor	Multiply by the 3 percent rural add-on	Proposed CY 2017 rural NRS conversion factor
$52.40	× 1.03	$53.97	$51.38	× 1.03	$52.92

TABLE 21—PROPOSED CY 2017 NRS PAYMENT AMOUNTS FOR SERVICES PROVIDED IN A RURAL AREA

		For HHAs that DO submit quality data		For HHAs that DO NOT submit quality data	
Severity level	Points (scoring)	Relative weight	Proposed CY 2017 NRS payment amounts for rural areas	Relative weight	Proposed CY 2017 NRS payment amounts for rural areas
1	0	0.2698	$14.56	0.2698	$14.28
2	1 to 14	0.9742	52.58	0.9742	51.55
3	15 to 27	2.6712	144.16	2.6712	141.36
4	28 to 48	3.9686	214.19	3.9686	210.02
5	49 to 98	6.1198	330.29	6.1198	323.86
6	99+	10.5254	568.06	10.5254	557.00

D. Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the national, standardized 60-day case-mix and wage-adjusted episode payment amounts in the case of episodes that incur unusually high costs due to patient care needs. Prior to the enactment of the Affordable Care Act, section 1895(b)(5) of the Act stipulated that projected total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. In the July 3, 2000 Medicare Program; Prospective Payment System for Home Health Agencies final rule (65 FR 41188 through 41190), we described the method for determining outlier payments. Under this system, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost is the sum of the national wage-adjusted per-visit payment amounts for all visits delivered during the episode. The outlier threshold for each case-mix group or Partial Episode Payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

In the CY 2010 HH PPS proposed rule (74 FR 40948), we stated that outlier payments increased as a percentage of total payments from 4.1 percent in CY 2005, to 5.0 percent in CY 2006, to 6.4 percent in CY 2007 and that this excessive growth in outlier payments was primarily the result of unusually high outlier payments in a few areas of the country. In that discussion, we noted that despite program integrity efforts associated with excessive outlier payments in targeted areas of the country, we discovered that outlier expenditures still exceeded the 5 percent target in CY 2007 and, in the absence of corrective measures, would continue do to so. Consequently, we assessed the appropriateness of taking action to curb outlier abuse. As described in the HH PPS final rule (74 FR 58080 through 58087), to mitigate possible billing vulnerabilities associated with excessive outlier payments and adhere to our statutory limit on outlier payments, we finalized an outlier policy that included a 10 percent agency-level cap on outlier payments. This cap was implemented in concert with a reduced FDL ratio of

0.67. These policies resulted in a projected target outlier pool of approximately 2.5 percent. (The previous outlier pool was 5 percent of total home health expenditures). For CY 2010, we first returned the 5 percent held for the previous target outlier pool to the national, standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor. Then, we reduced the CY 2010 rates by 2.5 percent to account for the new outlier pool of 2.5 percent. This outlier policy was adopted for CY 2010 only.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, and required the Secretary to reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by re-designating the existing language as section 1895(b)(5)(A) of the Act, and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes may not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added subparagraph (B) which capped outlier payments as a percent of total payments for each HHA at 10 percent.

As such, beginning in CY 2011, our HH PPS outlier policy is that we reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

2. Proposed Changes to the Methodology Used To Estimate Episode Cost

As stated earlier, an episode's estimated cost is determined by multiplying the national wage-adjusted per-visit payment amounts by discipline by the number of visits by discipline reported on the home health claim. An episode's estimated cost is then used to determine whether an episode will receive an outlier payment and the amount of the outlier payment. Analysis of CY 2015 home health claims data indicates that there is significant variation in the visit length by discipline for outlier episodes. Those agencies with 10 percent of their total payments as outlier payments are providing shorter but more frequent skilled nursing visits than agencies with less than 10 percent of their total payments as outlier payments (see Table 22).

TABLE 22—AVERAGE NUMBER AND LENGTH OF SKILLED NURSING VISITS BY THE PERCENTAGE OF OUTLIER PAYMENTS TO TOTAL PAYMENTS AT THE AGENCY LEVEL (CURRENT OUTLIER METHODOLOGY), CY 2015

	Avg. # of skilled nursing visits	Avg. minutes per skilled nursing visit
<1% Total Outlier Payments	21.7	47.2
1% to <5% Total Outlier Payments	26.7	44.0
5% to <10% Total Outlier Payments	26.7	44.3
10% Total Outlier Payments	44.5	35.6

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

As shown in Table 23, the number of skilled nursing visits is significantly higher than the number of visits for the five other disciplines of care and therefore, outlier payments are predominately driven by the provision of skilled nursing services.

TABLE 23—AVERAGE NUMBER OF VISITS BY DISCIPLINE FOR OUTLIER EPISODES

Discipline	Average number of visits
Home health aide	8.8
Medical social services	0.3
Occupational therapy	2.3
Physical therapy	5.1
Skilled nursing	34.0
Speech-language pathology	0.7

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

As a result of the analysis of CY 2015 home health claims data, we are concerned the current methodology for calculating outlier payments may create a financial disincentive for providers to treat medically complex beneficiaries who require longer visits. The home health environment differs from hospitals and other institutional environments. In the home setting, the patient has a greater role in determining how, when, and even if, certain interventions will be implemented. Individual skill, cognitive and functional ability, and financial resources affect the ability of home health patients to safely manage their health care needs, interventions, and medication regimens.[5] Clinically complex patients generally use more health services, have functional limitations, need more assistance to perform activities of daily living (ADLs), require social support and community resources, and require more complex medical interventions.[6] For example, patients using home total parenteral nutrition (TPN) must cope with very high-tech needs at home and because of the complexity of TPN therapy, a high level of knowledge and expertise is required in the clinical management of these patients.[7] In addition to the direct patient care needs, patient education aims at instruction on the care of the central venous access device, administration procedures and monitoring for complications, overall well-being, parenteral nutrition composition and frequency, test results, medications, practical and psychosocial issues.[8] Visit frequency for home TPN patients varies and length of nursing visits can range from 15 minutes for infusion site and catheter assessment to 10 hours for direct patient care.[9] For those patients who require assistance with bathing, research has shown older persons are more likely to have negative expectations regarding the inevitability of further physical decline after they experience bathing difficulties.[10] As older home health patients decline, they may be more likely to accept assistance with bathing and this may have the unintended consequence of reliance on bathing assistance, which could lead to further functional decline in the performance of other ADLs. To mitigate further functional decline, home health nursing intensity and visit time increases as home nursing interventions are targeted to work with patients and caregivers on bathing sub-tasks, assistance in modifying the home environment through the acquisition and use of adaptive equipment and devising strategies to support patients in dealing with pain and fatigue that could prevent independent bathing.[11]

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[5] Ibid.

[6] Rich, E., Lipson, D., Libersky, J., Parchman, M. (2012). Coordinating Care for Adults with Complex Care Needs in the Patient-Centered Medical Home: Challenges and Solutions. AHRQ Publication No. 12–0010, *https://pcmh.ahrq.gov/page/coordinating-care-adults-complex-care-needs-patient-centered-medical-home-challenges-and*.

[7] Huisman-deWaal, G. Achterberg, T., Jansen, J., Wanten, G., Schoonhoven, L. (2010). "High-tech" home care: Overview of professional care in patients on home parenteral nutrition and implications for nursing care. Journal of Clinical Nursing. (20), 2125–2134.

Higher nursing visit intensity and longer visits are a generally a response to instability of the patient's condition, and/or inability to effectively and safely manage their condition and self-care activities; therefore, more clinically complex, frail, elderly patients will require more intensive and frequent home health surveillance, increased home health care utilization, and costs.[12] [13]

In addition to the clinical information described above, Mathematica Policy Research published a report in 2010 titled "Home Health Independence Patients: High Use, but Not Financial Outliers."[14] In this report, Mathematica described their analysis of the relationships among the proxy demonstration target group for the Home Health Independence Demonstration, patients who receive outlier payments, and the agencies that serve them. As part of their research, Mathematica examined the degree of overlap between the proxy demonstration target group, who are ill, permanently disabled beneficiaries, and those beneficiaries receiving outlier payments. The study found that "Only a small fraction of proxy demonstration patients generate outlier payments and that differences between the proxy demonstration and outlier patient groups examined in this study suggest that outlier payments are not generally being used to serve the types of severely, permanently disabled beneficiaries that were addressed by the demonstration concept."

Therefore, we are proposing to change the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. Using this approach, we would convert the national per-visit rates in section III.C.3. into per 15 minute unit rates (see Table 24). The new per-unit rates by discipline would then be used, along with the visit length data by discipline reported on the home health claim in 15 minute increments (15 minutes = 1 unit), to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. We note that this change in the methodology would be budget neutral as we would still target to pay out 2.5 percent of total payments as outlier payments in accordance with section 1895(b)(5)(A) of the Act, which requires us to pay up to, but no more than, 2.5 percent of total HH PPS payments as outlier payments.

TABLE 24—PROPOSED COST-PER-UNIT PAYMENT RATES FOR THE CALCULATION OF OUTLIER PAYMENTS

Visit type	Proposed CY 2017 national per-visit payment rates	Average minutes-per-visit	Cost-per-unit (1 unit = 15 minutes)
Home health aide	$64.09	62.2	$15.46
Medical social services	226.87	56.4	60.34
Occupational therapy	155.77	47.1	49.61
Physical therapy	154.72	46.6	49.80
Skilled nursing	141.54	44.7	47.50
Speech-language pathology	168.16	48.1	52.44

SOURCE: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

NOTE(S): Excludes LUPAs.

We believe that this proposed change to the outlier methodology will result in more accurate outlier payments where the calculated cost per episode accounts for not only the number of visits during an episode of care, but also the length of the visits performed. This, in turn, may address some of the findings from the home health study, where margins were lower for patients with medically complex needs that typically require longer visits, thus potentially creating an incentive to treat less complex patients.

Table 25 shows the difference in the average number of visits and the average minutes per visit for outlier episodes under the current outlier methodology and the proposed outlier methodology by the percentage of outlier payments to total payments at the agency level.

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[8] Ibid.

[9] Piamjariyakul, U., Ross, V., Yadrich, D.M., Williams, A., Howard, L., Smith, C. (2010). Complex Home Care: Part I-Utilization and Costs to Families for Health Care Services Each Year. Nursing Economics. 28(4), 255–263

[10] Friedman, B., Yanen, L., Liebel, D., Powers, B. (2014). Effects of Home Visiting Nurse Intervention versus Care as Usual on Individual Activities of Daily Living: A Secondary Analysis of a Randomized Trial. BMC Geriatrics. 14(24), 1–13.

[11] Ibid.

[12] Fried. L., Ferrucci, L., Darer, J., Williamson, J., Anderson, G. (2004). Untangling the Concepts of Disability, Frailty and Comorbidity: Implications for Improved Targeting and Care. Journal of Gerontology. 59(3), 255–263.

[13] Riggs, J., Madigan, E., Fortinsky, R. (2011). Home Health Care Nursing Visit Intensity and Heart Failure Patient Outcomes. Home Health Care Managing Practice. 23(6), 412–420.

[14] Cheh, Valerie and Schurrer, John. Home Health Independence Patients: High Use, but Not Financial Outliers, Report to Centers for Medicare and Medicaid, Mathematical Policy Research. March 31, 2010.

TABLE 25—AVERAGE NUMBER OF VISITS AND MINUTES PER VISIT BY THE PERCENTAGE OF OUTLIER PAYMENTS TO TOTAL PAYMENTS AT THE AGENCY LEVEL FOR OUTLIER EPISODES FOR THE CURRENT AND PROPOSED OUTLIER METHODOLOGIES, CY 2015

	Current Outlier Methodology (Cost per Visit)		Proposed Outlier Methodology (Cost per Unit)	
	Avg. # of visits	Avg. minutes per visit	Avg. # of visits	Avg. minutes per visit
<1% Total Outlier Payments	39.7	48.9	38.5	52.6
1% to <5% Total Outlier Payments	44.7	49.2	43.5	52.0
5% to <10% Total Outlier Payments	44.7	49.6	54.8	55.2
10% Total Outlier Payments	60.7	44.0	56.4	65.6

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

Analysis of the impact of the change from a cost-per-visit to a cost-per-unit approach indicates that approximately two-thirds of outlier episodes under the cost-per-unit approach would have still received outlier payments under the current cost-per-visit approach, while about one-third of outlier episodes under the current cost per visit approach would not receive outlier payments under the cost-per-unit approach. Table 26 shows the average number of visits and the visit length for the episodes that would receive outlier payments under the current cost-per-visit approach, but not under the proposed cost-per-unit approach, as well as the average number of visits and the visit length for the episodes that would receive outlier payments under the proposed cost-per-unit approach, but not under the current cost-per-visit approach. Those episodes that would only receive outlier payments under the current cost-per-visit approach have less average resource use (calculated by multiplying the number of visits with the number of minutes) than those episodes that would only receive outlier payments under the proposed cost-per-unit approach. These results indicate that the change from the current cost-per-visit methodology to the proposed cost-per-unit methodology would result in more accurate outlier payments that better account for the intensity of the visits performed rather than only visit volume.

TABLE 26—AVERAGE NUMBER OF VISITS AND VISIT LENGTH FOR EPISODES THAT RECEIVE OUTLIER PAYMENTS ONLY UNDER THE CURRENT OUTLIER METHODOLOGY AND FOR EPISODES THAT RECEIVE OUTLIER PAYMENTS ONLY UNDER THE PROPOSED OUTLIER METHODOLOGY, CY 2015

	Episodes that only would receive outlier payments under the current methodology		Episodes that only would receive outlier payments under the proposed methodology	
	Avg. # of visits	Avg. minutes per visit	Avg. # of visits	Avg. minutes per visit
<1% Total Outlier Payments	36.8	39.9	29.8	63.4
1% to <5% Total Outlier Payments	37.6	38.5	30.6	65.6
5% to <10% Total Outlier Payments	43.8	36.4	30.2	85.9
10% Total Outlier Payments	46.1	27.5	31.9	104.5

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

In addition, we examined the impact of changing from the current cost-per-visit methodology to the proposed cost-per-unit methodology on a subset of the vulnerable patient populations identified in the home health study. Our simulations indicate that certain subgroups identified in the home health study may benefit from the change from the current outlier methodology to the proposed outlier methodology. Table 27 shows some of the vulnerable patient populations that may benefit from the proposed changes to the outlier methodology. As shown in Table 27, preliminary analysis indicates that a larger percentage of episodes of care for patients with a fragile overall health status will qualify for outlier payments under the proposed methodology than under the current methodology (24.1 percent versus 20.1 percent). Similarly, a larger percentage of episodes of care for patients who need assistance with bathing will qualify for outlier payments under the proposed methodology than under the current methodology (29.1 percent versus 27.0 percent). In addition, a larger percentage of episodes of care for patients who need caregiver assistance or who have surgical wounds will qualify for outlier payments under the proposed methodology versus under the current methodology (7.7 percent versus 6.7 percent and 19.0 percent versus 18.1 percent, respectively). Furthermore, there are small increases in the percentage of episodes of care that would qualify for outlier payments for the patients who need parenteral nutrition or have poorly controlled cardiac dysrhythmia or pulmonary disorders. These results suggest that the proposed change to the outlier methodology may address some of the findings from the home health study and may alleviate potential financial disincentives to treat patients with medically complex needs.

TABLE 27—IMPACT OF THE PROPOSED OUTLIER METHODOLOGY CHANGE ON SUBGROUPS OF VULNERABLE PATIENT POPULATIONS IDENTIFIED IN THE HOME HEALTH STUDY

Subgroups identified in the home health study	Overall percentage for all non-LUPA episodes (%)	Percent of outliers based on cost-per-visit approach (%)	Percent of outliers based on cost-per-unit approach (%)
Needs caregiver assistance	6.8	6.7	7.7
Fragile-serious overall status	21.9	20.1	24.1
Needs assistance with bathing	20.1	27.0	29.1
Parenteral Nutrition	0.2	0.2	0.4
Poorly Controlled Cardiac Dysrhythmia	4.3	3.4	3.8
Poorly Controlled Pulmonary Disorder	7.8	5.4	6.0
Surgical Wound	17.6	18.1	19.0

Source: CY 2015 home health claims data from the standard analytic file (as of December 31, 2015) for which we had a linked OASIS assessment.

Note(s): These results are based on simulations using CY 2015 utilization and the CY2017 payment parameters.

In concert with our proposal to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, we are proposing to implement a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes. Specifically, we propose to limit the amount of time per day (summed across the six disciplines of care) to 8 hours or 32 units per day when estimating the cost of an episode for outlier calculation purposes. We note that this proposal is consistent with the definition of "part-time" or "intermittent" set out in section 1861(m) of the Act, which limits the amount of skilled nursing and home health aide minutes combined to less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). We also note that we are not limiting the amount of care that can be provided on any given day. We are only limiting the time per day that can be credited towards the estimated cost of an episode when determining if an episode should receive outlier payments and calculating the amount of the outlier payment. For instances when more than 8 hours of care is provided by one discipline of care, the number of units for the line item will be capped at 32 units for the day for outlier calculation purposes. For rare instances when more than one discipline of care is provided and there is more than 8 hours of care provided in one day, the episode cost associated with the care provided during that day will be calculated using a hierarchical method based on the cost per unit per discipline shown in Table 24. The discipline of care with the lowest associated cost per unit will be discounted in the calculation of episode cost in order to cap the estimation of an episode's cost at 8 hours of care per day. For example, if an HHA provided 4.5 hours of skilled nursing and 4.5 hours of home health aide services, all 4.5 hours of skilled nursing would be counted in the episode's estimated cost and 3.5 hours of home health aide services would be counted in the episode's estimated cost (8 hours − 4.5 hours = 3.5 hours) since home health aide services has a lower cost-per-unit than skilled nursing services.

We note that preliminary analysis suggests that this proposed cap will have a limited impact on episodes overall. Out of approximately 5.4 million episodes in our preliminary analytic file for 2015, only 15,384 episodes or 0.28 percent of all home health episodes reported instances where over 8 hours of care were provided in a single day (which could have resulted from data entry errors as we currently do not use visit length for payment). Of those 15,384 episodes, only 1,591 would be outlier episodes under the proposed outlier methodology. Therefore, we estimate that only 1,600 episodes or so, out of 5.4 million episodes, would be impacted due to the proposed 8 hour cap.

3. Proposed Fixed Dollar Loss (FDL) Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount.

In the CY 2011 HH PPS final rule (75 FR 70398), in targeting total outlier payments as 2.5 percent of total HH PPS payments, we implemented an FDL ratio of 0.67, and we maintained that ratio in CY 2012. Simulations based on CY 2010 claims data completed for the CY 2013 HH PPS final rule showed that outlier payments were estimated to comprise approximately 2.18 percent of total HH PPS payments in CY 2013, and as such, we lowered the FDL ratio from 0.67 to 0.45. We stated that lowering the FDL ratio to 0.45, while maintaining a loss-sharing ratio of 0.80, struck an effective balance of compensating for high-cost episodes while allowing more episodes to qualify as outlier payments (77 FR 67080). The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

For this proposed rule, simulating payments using preliminary CY 2015 claims data (as of December 31, 2015) and the CY 2016 payment rates (80 FR 68649 through 68652), we estimate that outlier payments in CY 2016 would comprise 2.23 percent of total payments. Based on simulations using CY 2015 claims data and the CY 2017 payment rates in section III.C.3 of this proposed rule, we estimate that outlier payments would comprise approximately 2.58 percent of total HH PPS payments in CY 2017 under the current outlier methodology, a percent change of approximately 15.7 percent. This increase is attributable to the increase in the national per-visit amounts through the rebasing adjustments and the decrease in the national, standardized 60-day episode payment amount as a result of the rebasing adjustment and the nominal case-mix growth reduction.

Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we are proposing a change to the FDL ratio for CY 2017 as we believe that maintaining an FDL ratio of 0.45 with a loss-sharing ratio of 0.80 is no longer appropriate given the percentage of outlier payments projected for CY 2017. We note that we are not proposing a change to the loss-sharing ratio (0.80) in order for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.) Under the current outlier methodology, the FDL ratio would need to be changed from 0.45 to 0.48 to pay up to, but no more than, 2.5 percent of total payments as outlier payments. Under the proposed outlier methodology which would use a cost per unit rather than a cost per visit when calculating episode costs, we estimate that we will pay out 2.74 percent in outlier payments in CY 2017 using an FDL ratio of 0.48 and that the FDL ratio will need to be changed to 0.56 to pay up to, but no more than, 2.5 percent of total payments as outlier payments.

Therefore, in addition to the proposal to change the methodology used to calculate outlier payments, we are proposing to change the FDL ratio from 0.45 to 0.56 for CY 2017. We note that in the final rule, we will update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2015 claims data as of June 30, 2016) and therefore, we may adjust the final FDL ratio accordingly. We invite public comments on the proposed changes to the outlier payment calculation methodology and the associated changes in the regulations text at § 484.240 as well as the proposed change to the FDL ratio.

E. Proposed Payment Policies for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device

1. Background

Negative pressure wound therapy (NPWT) is a medical procedure in which a vacuum dressing is used to enhance and promote healing in acute, chronic, and burn wounds. The therapy involves using a sealed wound dressing attached to a pump to create a negative pressure environment in the wound. Applying continued or intermittent vacuum pressure helps to increase blood flow to the area and draw out excess fluid from the wound. Moreover, the therapy promotes wound healing by preparing the wound bed for closure, by reducing edema, by promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. The wound type and/or the location of the wound determine whether the vacuum can either be applied continuously or intermittently. NPWT can be utilized for varying lengths of time, as indicated by the severity of the wound, from a few days of use up to a span of several months.

In addition to the conventional NPWT systems classified as durable medical equipment (DME), NPWT can also be performed with a single-use disposable system that consists of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy. These disposable systems consist of a small pump, which eliminates the need for a bulky canister. Unlike conventional NPWT systems classified as DME, disposable NPWT systems have a preset continuous negative pressure, there is no intermittent setting, they are pocket-sized and easily transportable, and they are generally battery-operated with disposable batteries.[15]

Section 1895 of the Act requires that the HH PPS includes payment for all covered home health services. Section 1861(m) of the Act defines what items and services are considered to be "home health services" when furnished to a Medicare beneficiary under a home health plan of care when provided in the beneficiary's place of residence. Those services include:

- Part-time or intermittent nursing care
- Physical or occupational therapy or speech-language pathology services
- Medical social services
- Part-time or intermittent services of a home health aide
- Medical supplies
- A covered osteoporosis drug
- Durable medical equipment (DME)

The unit of payment under the HH PPS is a national, standardized 60-day episode payment amount with applicable adjustments. The national, standardized 60-day episode payment amount includes costs for the home health services outlined above per section 1861(m) of the Act, except for DME and the covered osteoporosis drug. Section 1814(k) of the Act specifically excludes DME from the national, standardized 60-day episode rate and consolidated billing requirements. DME continues to be paid outside of the HH PPS. The cost of the covered osteoporosis drug (injectable calcitonin), which is covered where a woman is postmenopausal and has a bone fracture, is also not included in the national, standardized 60-day episode payment amount, but must be billed by the HHA while a patient is under a home health plan of care since the law requires consolidated billing of osteoporosis drugs. The osteoporosis drug itself continues to be paid on a reasonable cost basis.

Medical supplies are included in the definition of "home health services" and the cost of such supplies is included in the national, standardized 60-day episode payment amount. Medical supplies are items that, due to their therapeutic or diagnostic characteristics, are essential in enabling HHA personnel to conduct home visits or to carry out effectively the care the physician has ordered for the treatment or diagnosis of the patient's illness or injury. Supplies are classified into two categories, specifically:

- *Routine:* Supplies used in small quantities for patients during the usual course of most home visits; or
- *Non-routine:* Supplies needed to treat a patient's specific illness or injury in accordance with the physician's plan of care and meet further conditions.

Both routine and non-routine medical supplies are included in the national, standardized 60-day episode payment amount for every Medicare home health patient regardless of whether or not the patient requires medical supplies during the episode. The law requires that all medical supplies (routine and non-routine) be provided by the HHA while the patient is under a home health plan of care. A disposable NPWT system would be considered a non-routine supply for home health.

As required under sections 1814(a)(2)(C) and 1835(a)(2)(A) of the

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[15] Single use negative pressure wound therapy. CME Online. 2013 *www.pfiedler.com.*

Act, for home health services to be covered, the patient must receive such services under a plan of care established and periodically reviewed by a physician. As described in § 484.18 of the Medicare Conditions of Participation (CoPs), the plan of care that is developed in consultation with the agency staff, is to cover all pertinent diagnoses, including the types of services and equipment required for the treatment of those diagnoses as well as any other appropriate items, including DME. Consolidated billing requirements ensure that only the HHA can bill for home health services, with the exception of DME and therapy services provided by physicians, when a patient is under a home health plan of care. The types of service most affected by the consolidated billing edits tend to be non-routine supplies and outpatient therapies, since these services are routinely billed by providers other than HHAs, or are delivered by HHAs to patients not under home health plans of care.

As provided under section 1834(k)(5) of the Act, a therapy code list was created based on a uniform coding system (that is, the HCPCS) to identify and track these outpatient therapy services paid under the Medicare Physician Fee Schedule (MPFS). The list of therapy codes, along with their respective designation, can be found on the CMS Web site, specifically at *http://www.cms.hhs.gov/TherapyServices/05_Annual_Therapy_Update.asp#TopOfPage*. Two of the designations that are used for therapy services are: "Always therapy" and "sometimes therapy." An "always therapy" service must be performed by a qualified therapist under a certified therapy plan of care, and a "sometimes therapy" service may be performed by physician or a non-physician practitioner outside of a certified therapy plan of care. CPT codes 97607 and 97608 are categorized as a "sometimes" therapy, which may be performed by either a physician or a non-physician practitioner outside of a certified therapy plan of care, as described in section 200.9 of Chapter 4 of the Medicare Claims Processing Manual.[16]

2. The Consolidated Appropriations Act of 2016

As mentioned in section III.A.1 above, for patients under a home health plan of care, payment for part-time or intermittent skilled nursing, physical therapy, speech-language pathology, occupational therapy, medical social services, part-time or intermittent home health aide visits, and routine and non-routine supplies are included in the episode payment amount. A disposable NPWT system is currently considered a non-routine supply and thus payment for the disposable NPWT system is included in the episode payment amount. The Consolidated Appropriations Act of 2016 (Pub. L 114–113) amends both section 1834 of the Act (42 U.S.C. 1395m) and section 1861(m)(5) of the Act (42 U.S.C. 1395x(m)(5)), requiring a separate payment to a HHA for an applicable disposable device when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. Section 1834(s)(2) of the Act defines an applicable device as a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy used in lieu of a conventional NPWT DME system.

As required by the Consolidated Appropriations Act of 2016 (Pub. L 114–113), the separate payment amount for NPWT using a disposable system is to be set equal to the amount of the payment that would be made under the Medicare Hospital Outpatient Prospective Payment System (OPPS) using the Level I Healthcare Common Procedure Coding System (HCPCS) code, otherwise referred to as Current Procedural Terminology (CPT–4) codes, for which the description for a professional service includes the furnishing of such a device.

Under the OPPS, CPT codes 97607 and 97608 (APC 5052—Level 2 Skin Procedures), include furnishing the service as well as the disposable NPWT device. The codes are defined as follows:

- HCPCS 97607—Negative pressure wound therapy, (for example, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.
- HCPCS 97608—Negative pressure wound therapy, (for example, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.

3. Proposed Payment Policies for NPWT Using a Disposable Device

For the purposes of paying for NPWT using a disposable device for a patient under a Medicare home health plan of care and for which payment is otherwise made under section 1895(b) of the Act, CMS is proposing that for instances where the sole purpose for an HHA visit is to furnish NPWT using a disposable device, Medicare will not pay for the visit under the HH PPS. Instead, we propose that since furnishing NPWT using a disposable device for a patient under a home health plan of care is to be paid separately, based on the OPPS amount, which includes payment for both the device and furnishing the service, the HHA must bill these visits separately under type of bill 34x (used for patients not under a HH plan of care, Part B medical and other health services, and osteoporosis injections) along with the appropriate HCPCS code (97607 or 97608). Visits performed solely for the purposes of furnishing NPWT using a disposable device are not to be reported on the HH PPS claim (type of bill 32x).

If NPWT using a disposable device is performed during the course of an otherwise covered HHA visit (for example, while also furnishing a catheter change), we propose that the HHA must not include the time spent furnishing NPWT in their visit charge or in the length of time reported for the visit on the HH PPS claim (type of bill 32x). Providing NPWT using a disposable device for a patient under a home health plan of care will be separately paid based on the OPPS amount relating to payment for covered OPD services. In this situation, the HHA bills for NPWT performed using a disposable device under type of bill 34x along with the appropriate HCPCS code (97607 or 97608). Additionally, this same visit should also be reported on the HH PPS claim (type of bill 32x), but only for the time spent furnishing the services unrelated to the provision of NPWT.

As noted in section III.E.1, since these two CPT codes (97607 and 97608) are considered "sometimes" therapy codes, NPWT using a disposable device for patients under a home health plan of care can be performed, in accordance to State law, by a registered nurse, physical therapist, or occupational therapist and the visits would be reported on the type of bill 34x using revenue codes 0559, 042X, 043X. The descriptions for CPT codes 97607 and 97608 include performing a wound assessment, therefore we believe that it would only be appropriate for these visits to be performed by a registered nurse, physical therapist, or occupational therapist as defined in § 484.4 of the Medicare Conditions of Participation (CoPs).

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[16] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.*

The payment amount for both 97607and 97608 will be set equal to the amount of the payment that would be made under the OPPS and subject to the area wage adjustment policies in place under the OPPS, for CY 2017 and each subsequent year. Please see Medicare Hospital OPPS Web page for Addenda A and B at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html.* These addenda are a "snapshot" of HCPCS codes and their status indicators, APC groups, and OPPS payment rates that are in effect at the beginning of each quarter. Section 504(b)(1) of the Consolidated Appropriations Act of 2016 (Pub. L 114–113) amends section 1833(a)(1) of the Act, which requires that furnishing the NPWT using a disposable device be subject to beneficiary coinsurance in the amount of 20 percent. The amount paid to the HHA by Medicare will be equal to 80 percent of the lesser of the actual charge or the payment amount as determined by the OPPS for the year.

In order for a beneficiary to receive NPWT using a disposable device under the home health benefit, the beneficiary must also qualify for the home health benefit in accordance with the existing eligibility requirements. To be eligible for Medicare home health services, as set out in sections 1814(a) and 1835(a) of the Act, a physician must certify that the Medicare beneficiary (patient) meets the following criteria:

- Is confined to the home
- Needs skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or have a continuing need for occupational therapy
- Is under the care of a physician
- Receive services under a plan of care established and reviewed by a physician; and
- Has had a face-to-face encounter related to the primary reason for home health care with a physician or allowed Non-Physician Practitioner (NPP) within a required timeframe.

As set forth in §§ 409.32 and 409.44, to be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel. Additionally, care is deemed as "reasonable and necessary" based on information reflected in the home health plan of care, the OASIS as required by § 484.55, or a medical record of the individual patient. Coverage for NPWT using a disposable device will be determined based upon a doctor's order as well as patient preference. Research has shown that patients prefer wound dressing materials that afford the quickest wound healing, pain reduction, maximum exudate absorption to minimize drainage and odor, and they indicated some willingness to pay out of pocket costs.[17] Treatment decisions as to whether to use a disposable NPWT system versus a conventional NPWT DME system is determined by the characteristics of the wound, as well as, patient goals and preferences discussed with the ordering physician to best achieve wound healing and reduction.

We are soliciting public comment on all aspects of the proposed payment policies for furnishing a disposable NPWT device as articulated in this section as well as the corresponding proposed changes to the regulations at § 409.50 in section VII of this proposed rule.

F. Update on Subsequent Research and Analysis Related to Section 3131(d) of the Affordable Care Act

Section 3131(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), (collectively referred to as "The Affordable Care Act"), directed the Secretary of Health and Human Services (the Secretary) to conduct a study on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas and in treating beneficiaries with high levels of severity of illness and to submit a Report to Congress on the study's findings and recommendations. As part of the study, the Affordable Care Act stated that we may also analyze methods to potentially revise the home health prospective payment system (HH PPS). In the CY 2016 HH PPS proposed rule (80 FR 39840), we summarized the Report to Congress on the home health study, required by section 3131(d) of the Affordable Care Act, and provided information on the initial research and analysis conducted to potentially revise the HH PPS case-mix methodology to address the home health study findings outlined in the Report to Congress. In this proposed rule, we are providing an update on additional research and analysis conducted on the Home Health Groupings Model (HHGM), one of the model options referenced in the CY 2016 HH PPS proposed rule (80 FR 39866).

The premise of the HHGM starts with a clinical foundation where home health episodes are grouped by primary diagnosis based on what home health interventions would be required during the episode of care. In addition to the clinical groupings, the HHGM incorporates other information from the OASIS and claims data to further group home health episodes for payment. Each home health episode is categorized into different sub-groups within each of the five categories below:

- *Timing* (early or late; that is, episode is placed into 1 of 2 groups)
- *Referral source* (community, acute, or post-acute admission source; that is, episode is placed into 1 of 3 groups)
- *Clinical grouping* (musculoskeletal rehab, neuro/stroke rehab, wounds, MMTA, behavioral, or complex; that is, episode is placed into 1 of 6 groups)
- *Functional/cognitive level* (low, medium, or high; that is, episode is placed into 1 of 3 groups)
- *Comorbidity adjustment* (first, second, or third, tier based on secondary diagnoses; that is, episode is placed into 1 of 3 groups)

In total there would be 324 possible payment groupings an episode can be grouped into under the HHGM. Unlike the current payment model, the HHGM does not rely on the number of therapy visits performed to influence payment.

Similar to the current payment system, episodes under the HHGM are first classified as "early" or "late" depending on when they occur within a sequence of adjacent episodes, as outlined in our regulations at § 484.230. Currently, the first two 60-day episodes of care are considered "early" and third or later 60-day episodes of care are considered "late". However, recent analysis shows that there is a substantial difference in the number of visits that occur during the first 30 days of a 60-day episode of care compared to the second 30 days in a 60-day episode of care (see Figure 4, below).

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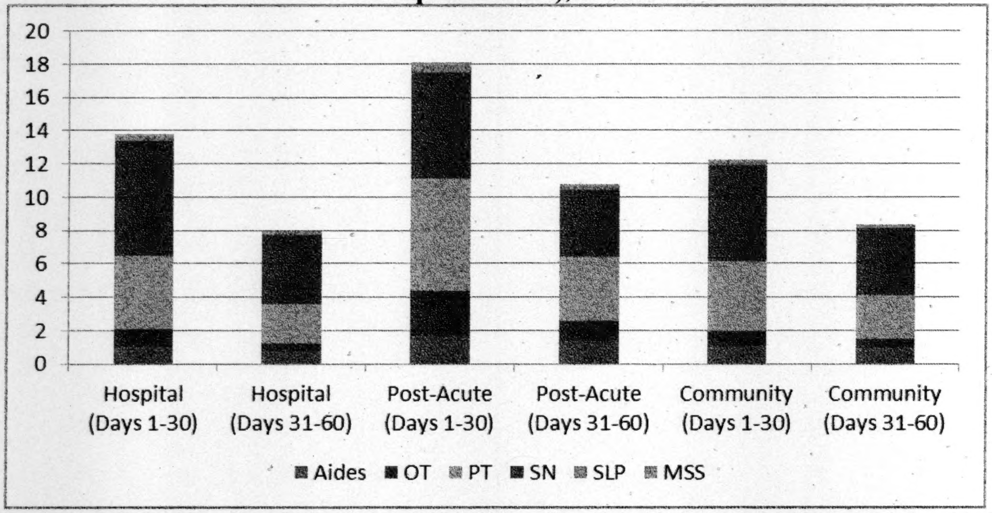
[17] Corbett, L., Ennis, W. (2014). What Do Patients Want? Patient Preferences in Wound Care. 3(8), 537–543.

Figure 4: Average Visits for the First 30 Days Versus Second 30 Days of a 60-day Episode of Care (First Episodes that Last 60 days with No Intervening Hospitalization), CY 2013



Source: CY 2013 home health claims data for claims with a through date on or before December 31, 2013 from the June 30, 2014 standard analytic file for which there was a linked OASIS assessment.
Note(s): Low-utilization payment adjustment (LUPA) and outlier episodes were excluded from this analysis.

Given the differences in the number of visits occurring in the first 30 days versus the second 30 days in a 60-day episode of care, and to better account for the relationship between episode characteristics and episode cost, we modeled all episodes as 30-day episodes of care, instead of 60-day episodes of care as in the current payment system. Under the HHGM, the first 30-day episode in a sequence of adjacent episodes was classified as an early episode. All subsequent episodes in a sequence (second or later) of adjacent episodes were classified as late episodes if separated by no more than a 60-day gap in care.

After taking into account whether the 30-day episode of care was "early" versus "late", each episode was then classified into one of three referral source categories depending on whether the beneficiary was admitted from an acute or post-acute care facility within 14 days prior to being admitted to home health (community, acute, or post-acute). Patients admitted to home health from the community, an acute setting of care, or a post-acute setting of care had different observable patterns of resource use and thus, under the HHGM, episodes of care for those patients would be paid differently.

We then grouped episodes into one of six clinical groups based on the primary diagnosis listed on the OASIS for each episode. We created these groups to describe the most common types of care that HHAs provide. We have reviewed all possible ICD–9–CM codes that could be recorded on the OASIS and assigned each code into one of the following clinical groups: Musculoskeletal Rehabilitation; Neuro/Stroke Rehabilitation; Wound Care; Medication Management, Teaching and Assessment (MMTA); Behavioral Health Care; and Complex Medical Care.

The HHGM designates a functional/cognitive level for each episode based on items identified on the OASIS that impact resource use. Using home health episodes from 2013, we estimated a regression model that determines the relationship between the responses for certain OASIS items and resource use.[18] The coefficients from the regression show how much more or less, on average, an episode's resource use is depending on responses to these items which is then used to predict resource use for each individual episodes. Ranking the episodes by predicted resource use and then identifying thresholds that divides episodes into three groups of roughly the same size allows us to assign each episode to into a low, medium or high functional/cognitive level.

Finally, our exploratory analyses have determined that secondary diagnoses (comorbidities) provide additional information that can predict resource use even after controlling for episode timing, referral source, the clinical grouping (based in the patient's primary diagnosis) and functional/cognitive level. Therefore, we further differentiated episodes into based on the presence of certain secondary diagnoses. We explored two options. For the first option we determined the commonly occurring comorbidities (incidence of over 0.1 percent) reported on the OASIS that were also associated with above average resource use. We then divided the comorbidities into a low or high group based on average resource use associated with the comorbidity. We then placed episodes into three tiers: Episodes for beneficiaries with no comorbidities reported on the OASIS in the low or high group (Tier 1); episodes for beneficiaries with comorbidities in the low, but not high group as reported on the OASIS (Tier 2); and episodes for beneficiaries with comorbidities in the high group reported on the OASIS (Tier 3). For the second option, we used the major complication or comorbidity (MCC) and complication and comorbidity (CC) list from the Inpatient Prospective Payment System (IPPS).

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[18] "Resource use" is an estimate of the cost of an episode. It is measured by multiplying the number of minutes of services that occur during an episode by a wage rate for the disciplines providing the care.

Using the CC and MMC list we placed episodes into three tiers: Episodes where beneficiaries had no MCC or CC diagnoses reported on either the OASIS or any inpatient or professional claim within 90 days of the start of home care (Tier 1); episodes where beneficiaries had CC but no MCC diagnoses reported on either the OASIS or any inpatient or professional claim within 90 days of the start of home care (Tier 2); and episodes where beneficiaries had at least one MCC diagnosis reported on either the OASIS or any inpatient or professional claim within 90 days of the start of home care (Tier 3).

We determined the case-mix weight for each of the 324 different HHGM payment groups by estimating a regression between episode resource use and binary variables controlling for the five dimensions described above (episode timing, admission source, HHGM clinical group, functional/cognitive level, and comorbidities). After estimating this model on home health episodes from 2013 (excluding LUPA and outlier episodes), we then used the results of the model to predict the expected average resource use of each episode based on these six characteristics. We divide the predicted resource use of each episode by the overall average resource use (of all 2013 episodes) to calculate the average case-mix of all episodes within a particular payment group (that is, each combination of the sub-groups within the five main groups). That case-mix weight is then used to adjust the base payment rate to then determine each episode's payment.

In many ways, the structure of the HHGM is similar to the current payment system. However, by either adding to or removing certain components of the current payment system, the HHGM could help to strengthen the HH PPS by addressing the margin differences noted in the home health study and by removing unintended financial incentives (for example, the current therapy thresholds). As noted in the 3131(d) study, margin differences exist across beneficiary characteristics such as parenteral nutrition, traumatic wounds, whether bathing assistance was needed, and admission source. These margin differences would be addressed by moving to a HHGM approach where those characteristics are better accounted for in the model. Additionally, the HHGM aligns with how clinicians generally identify the types of patients they see in home health, which, in turn, better defines the home health benefit in a more transparent manner so that the payer understands the primary reason for home care. We feel that the HHGM will address the findings highlighted in the 3131(d) report, specifically improving the payment accuracy for purchased home health services, promote fair compensation to HHAs, and increase the quality of care for beneficiaries. We plan to release a more detailed Technical Report in the future on this additional research and analysis conducted on the HHGM. When we release the technical report, we are also planning to release a list of the ICD–9–CM and ICD–10–CM codes assigned to each of the clinical groups within the HHGM to further assist the industry in analyzing the HHGM model. While we are not soliciting comments on the HHGM in this proposed rule, once the Technical Report is released, we will post a link on our Home Health Agency (HHA) Center Web site (*https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html*) to receive comments and feedback on the model.

FF. Update on Future Plans To Group HH PPS Claims Centrally During Claims Processing

In the CY 2011 HH PPS proposed rule (75 FR 43236) we solicited comments on potential plans to group HH PPS claims centrally during claims processing and received many comments in support of this initiative. In grouping HH PPS Claims centrally during processing, we are describing a process whereby all of the information necessary to group the claim and assign a Health Insurance Prospective Payment System (HIPPS) score which determines payment is available and processed within the Fiscal Intermediary Shared System (FISS). In that rule, we discussed the potential use of the treatment authorization field to group HH PPS claims within the claims processing system. In conducting further analysis, we determined that the use of the treatment authorization field was not a viable option. In our analysis, we determined that the information we planned to report in this field was not permitted by the Health Insurance Portability Accountability Act (HIPAA). In this section, we are soliciting comments on another process identified whereby all of the information necessary to group HH PPS claims occurs centrally during claims processing.

As we outlined in the previous rule, Medicare makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment amount that is adjusted for case-mix and geographic wage variations. The national, standardized 60-day episode payment amount includes services from the six HH disciplines (skilled nursing, HH aide, physical therapy, speech-language pathology, occupational therapy, and medical social services) and non-routine medical supplies. Durable medical equipment covered under HH is paid for outside the HH PPS payment. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification to assign patients to a home health resource group (HHRG). Clinical needs, functional status, and service utilization are computed from responses to selected data elements in the Outcome & Assessment Information Set (OASIS) instrument. On Medicare claims, the HHRGs are represented as HIPPS codes.

At a patient's start of care and before the start of each subsequent 60-day episode, the HHA is required to perform a comprehensive clinical assessment of the patient and complete the OASIS assessment instrument. The OASIS instrument collects data concerning 3 dimensions of the patient's condition: (1) Clinical severity (orthopedic, neurological or diabetic conditions, etc.); (2) Functional status (comprised of 6 activities of daily living (ADLs)); and (3) Service utilization (therapy visits provided during episode). HHAs enter data collected from their patients' OASIS assessments into a data collection software tool. For Medicare patients, the data collection software invokes HH PPS Grouper software to assign a HIPPS code to the patient's OASIS assessment. The HHA includes the HIPPS code assigned by HH PPS Grouper software on the Medicare HH PPS bill, ultimately enabling our claims processing system to reimburse the HHA for services provided to patients receiving Medicare home health services.

The HHA is separately required to electronically submit OASIS assessments for their Medicare and Medicaid patients to us. On the HH PPS Web site at *https://www.qtso.com/havendownload.html*, we provide a free OASIS assessment data collection tool (JHAVEN) which includes the HH PPS grouper software, a separate HH PPS grouper program which can be incorporated into an HHA's own data collection software, and HH PPS data specifications for use by HHAs or software vendors desiring to build their own HH PPS grouper. Most HHAs do not use the JHAVEN freeware, instead preferring to employ software vendors to create and maintain a customized assessment data collection tool which can be integrated into the HHA's billing software. Likewise, many vendors employed by HHAs do not utilize the

HH PPS grouper freeware, instead preferring to build their own HH PPS grouper from the data specifications which we provide.

Prior to the CY 2008, we made infrequent, minor changes to the HH PPS Grouper software. Since CY 2008, the HH PPS Grouper became more complex and more sensitive to annual diagnosis coding changes. As a result, in recent years, HHAs have been required to update their grouper software twice a year. Most HHAs employ software vendors to effectuate these updates. HHAs have expressed concerns to us that the bi-annual grouper updates coupled with the additional complexity of the grouper has increased provider and vendor burden.

We continue to identify OASIS assessments submitted with erroneous HIPPS codes through a process of comparing the submitted HIPPS code to the HIPPS code returned by our assessment system. These errors may occur when HHAs or their software vendors inaccurately replicate the HH PPS Grouper algorithm into the HHA's customized software. HHAs have expressed concerns that the HH PPS Grouper complexities increase their vulnerability to submit an inaccurate HIPPS code on the Medicare bill. We believe that embedding the HH PPS Grouper within the claims processing system would mitigate the provider's vulnerability and improve payment accuracy.

We recently implemented a process where we match the claim and the OASIS assessment in order to validate the HIPPS code on the Medicare bill. In addition, we have conducted an analysis and prototype testing of a java-based grouper with our FISS maintenance contractor. We believe that making additional enhancements to the claim and OASIS matching process would enable us to collect all of the other necessary information to assign a HIPPS code within the claims processing system. Adopting such a process would improve payment accuracy by improving the accuracy for HIPPS codes on bills, decrease costs, and burden to HHAs.

We are soliciting public comments on this potential enhancement as described above. If we implemented grouping HH PPS claims centrally within the claims processing system, the HHA would no longer have to maintain a separate process outside of our claims processing system, thus reducing the costs and burden to HHAs associated with the updates of the grouper software as well as the ongoing agency costs associated with embedding the HH PPS Grouper within JHAVEN. Finally, this enhancement would also address current payment vulnerabilities associated with the reporting of incorrect HIPPS codes on the claim.

IV. Proposed Provisions of the Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule, we implemented the HHVBP Model to begin on January 1, 2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and, (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, nine states were selected for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified HHAs that provide services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington (competing HHAs), are required to compete in the Model. Requiring all Medicare-certified HHAs in the selected states to participate in the Model ensures that: (1) There is no selection bias; (2) participating HHAs are representative of HHAs nationally; and, (3) there is sufficient participation to generate meaningful results.

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model will utilize the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act beginning in calendar year (CY) 2018 based on performance on applicable measures. Payment adjustments will be increased incrementally over the course of the HHVBP Model in the following manner: (1) A maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and, (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments will be based on each HHA's Total Performance Score (TPS) in a given performance year (PY) on (1) a set of measures already reported via OASIS and HHCAHPS for all patients serviced by the HHA, or determined by claims data and, (2) three New Measures where points are achieved for reporting data.

B. Smaller- and Larger-Volume Cohorts Proposals

The HHVBP Model compares a competing HHA's performance on quality measures against the performance of other competing HHAs within the same state and size cohort. Within each of the nine selected states, each competing HHA is grouped to either the smaller-volume cohort or the larger-volume cohort, as defined in § 484.305. The larger-volume cohort is defined as the group of competing HHAs within the boundaries of selected states that are participating in HHCAHPS in accordance with § 484.250 and the smaller-volume cohort is defined as the group of competing HHAs within the boundaries of selected states that are exempt from participation in HHCAHPS in accordance with § 484.250 (80 FR 68664). An HHA can be exempt from the HHCAHPS reporting requirements for a calendar year period if it has less than 60 eligible unique HHCAHPS patients annually as specified in § 484.250. In the CY 2016 HH PPS final rule, we finalized that when there are too few HHAs in the smaller-volume cohort in each state (such as when there are only one or two HHAs competing within a smaller-volume cohort in a given state) to compete in a fair manner, the HHAs would be included in the larger-volume cohort for purposes of calculating the TPS and payment adjustment percentage without being measured on HHCAHPS (80 FR 68664).

1. Proposal to Eliminate Smaller- and Larger-Volume Cohorts Solely for Purposes of Setting Performance Benchmarks and Thresholds

In the CY 2016 HH PPS final rule (80 FR 68681–68682), we finalized a scoring methodology for determining achievement points for each measure under which HHAs will receive points along an achievement range, which is a scale between the achievement threshold and a benchmark. The achievement thresholds are calculated as the median of all HHAs' performance on the specified quality measure during the baseline period and the benchmark is calculated as the mean of the top decile of all HHAs' performance on the specified quality measure during the baseline period.

We previously finalized that under the HHVBP Model, we would calculate both the achievement threshold and the benchmark separately for each selected state and for HHA cohort size. Under this methodology, benchmarks and achievement thresholds would be calculated for both the larger-volume cohort and for the smaller-volume cohort of HHAs in each state (which we defined in each state based on a baseline period from January 1, 2015 through December 31, 2015). We also finalized that, in determining improvement points for each measure, HHAs would receive points along an improvement range, which we defined as a scale indicating the change between an HHA's performance during the performance period and the HHA's performance in the baseline period divided by the difference between the benchmark and the HHAs performance in the baseline period. We finalized that both the benchmarks and the achievement thresholds would be calculated separately for each state and for HHA cohort size.

We finalized the above policies based on extensive analyses of the 2013–2014 OASIS, claims, and HHCAHPS archived data. We believed that these data were sufficient to predict the effect of using cohorts for benchmarking and threshold purposes because they have been used for several years in other CMS quality initiatives such as the Home Health Quality Reporting Program.

Since the publication of the CY 2016 HH PPS final rule, we have continued to evaluate the calculation of the benchmarks and achievement thresholds using the most recent CY 2015 data that is now available. We have calculated benchmarks and achievement thresholds for the OASIS measures for the smaller- and larger-volume cohorts and state-wide for each of the nine states using these data. Our review of the benchmarks and achievement thresholds for each of the cohorts and states indicates that the benchmark values for the smaller-volume cohorts varied considerably more from state-to-state than the benchmark values for the larger-volume cohorts. Some inter-state variation in the benchmarks and achievement thresholds for each of the measures was expected due to different state regulatory environments. However, the overall variation in these values was more than we expected, given the previous analyses we did. For example, with respect to the Improvement in Bed Transferring measure, we discovered that variation in the benchmark values between the smaller-volume cohorts was nearly three times greater than the variation in the benchmark values for the larger-volume cohorts or the statewide benchmarks. We also discovered that this large variation affected most of the measures. We are concerned that this high variation is not the result of expected differences like state regulatory policy, but is instead the result of (1) the cohort is so small that there are not enough HHAs in the cohort to calculate the values using the finalized methodology (mean of the top decile); or (2) the cohort is large enough to calculate the values using the finalized methodology, but there are not enough HHAs in the cohort to generate reliable values.

We have included three tables in this proposed rule to help illustrate this issue. Each of the three tables include the 10 benchmarks for the OASIS measures that were calculated for the Model using the 2015 QIES roll-up file data for each state. We did not include the claims measures and the HHCAHPS measures in this example because we do not have all of the 2015 data available. These three tables demonstrate the relationship between the size of the cohort and degree of variation of the different benchmark values among the states. Table 28, Table 29 and Table 30 represent the benchmarks for the OASIS measures for the smaller-volume cohorts, larger-volume cohorts and state-wide (which includes HHAs from both smaller- and larger-volume cohorts) respectively. For example, the difference in benchmark values for Iowa and Nebraska (two of the four states that have smaller-volume cohorts) for the Improvement in Bed Transfers measure is 13.1 (72.7 for Iowa and 85.8 for Nebraska) for the smaller-volume cohort (Table 28), 4.1 (78.1 for Iowa to 82.2 for Nebraska) for the larger-volume cohort (Table 29) and 5.5 (77.6 for Iowa to 83.1 for Nebraska) for the state level cohort (Table 30). We believe that the higher range for the smaller-volume cohorts is a result of there being a fewer number of HHAs in these cohorts.

TABLE 28—SMALLER-VOLUME COHORT BENCHMARKS

	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Oasis-Based Measures:									
Discharged to Community	77.0	88.8	73.6	82.0	....	75.1	81.1	79.4	
Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care	100.0	100.0	100.0	100.0	....	98.5	100.0	100.0	
Improvement in Ambulation- Locomotion	90.6	90.5	72.7	75.6	....	60.1	84.0	85.2	
Improvement in Bathing	82.0	91.2	79.5	71.8	....	72.1	77.4	81.5	
Improvement in Bed Transferring	68.8	80.4	72.7	74.1	....	55.1	85.8	79.0	
Improvement in Dyspnea	84.2	90.4	81.3	62.6	....	62.5	80.3	93.7	
Improvement in Management of Oral Medications	63.0	74.0	58.4	62.0	....	62.8	65.8	58.9	
Improvement in Pain Interfering with Activity	83.2	97.3	82.6	82.3	....	58.5	78.2	69.0	
Influenza Immunization Received for Current Flu Season	73.4	89.8	90.8	83.8	....	89.2	83.6	88.9	
Pneumococcal Polysaccharide Vaccine Ever Received	95.8	91.5	95.8	95.3	....	83.6	97.0	100.0	

TABLE 29—LARGER-VOLUME COHORT BENCHMARKS

	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Oasis-Based Measures:									
Discharged to Community	82.1	85.6	78.3	81.2	81.1	78.2	80.3	81.0	83.1
Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care	99.8	100.0	99.9	100.0	99.9	99.7	99.9	99.8	99.7
Improvement in Ambulation- Locomotion	76.4	92.4	76.7	76.1	76.5	75.2	80.8	77.2	70.8
Improvement in Bathing	84.2	94.2	81.9	81.0	81.0	78.9	86.6	83.5	77.7
Improvement in Bed Transferring	76.4	85.4	78.1	80.2	77.5	74.5	82.2	76.8	73.5
Improvement in Dyspnea	85.9	90.5	81.3	82.2	85.1	85.5	80.7	84.2	80.7
Improvement in Management of Oral Medications	69.4	80.5	68.1	73.2	71.7	63.9	68.1	72.2	64.0
Improvement in Pain Interfering with Activity	88.6	96.7	81.0	89.5	84.4	81.5	86.0	81.7	75.5
Influenza Immunization Received for Current Flu Season	88.0	93.3	88.1	90.1	87.9	88.0	95.2	88.2	87.0
Pneumococcal Polysaccharide Vaccine Ever Received	92.5	93.6	94.4	93.8	92.1	93.4	97.0	92.7	92.7

TABLE 30—STATE LEVEL COHORT BENCHMARKS

	State								
	AZ	FL	IA	MA	MD	NC	NE	TN	WA
Oasis-Based Measures:									
Discharged to Community	81.8	86.3	77.7	81.9	81.1	78.2	80.5	80.9	83.1
Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care	99.8	100.0	100.0	100.0	99.9	99.7	99.9	99.8	99.7
Improvement in Ambulation- Locomotion	77.5	92.1	76.2	76.3	76.5	75.2	82.9	77.9	70.8
Improvement in Bathing	84.1	93.8	81.8	80.3	81.0	78.9	84.6	83.5	77.7
Improvement in Bed Transferring	75.9	84.8	77.6	80.1	77.5	74.5	83.1	77.3	73.5
Improvement in Dyspnea	85.8	90.5	81.9	81.7	85.1	85.5	81.3	85.8	80.7
Improvement in Management of Oral Medications	69.1	79.6	67.3	72.0	71.7	64.1	68.3	72.2	64.0
Improvement in Pain Interfering with Activity	88.1	96.8	81.5	88.4	84.4	81.5	84.3	81.7	75.5
Influenza Immunization Received for Current Flu Season	87.6	92.9	88.9	90.1	87.9	88.3	94.4	88.2	87.0
Pneumococcal Polysaccharide Vaccine Ever Received	92.9	93.3	94.8	94.2	92.1	93.4	97.0	93.3	92.7

The three tables are based on the analysis using the most current data available. The results highlight that there is a greater degree of interstate variation in the benchmark values for the cohorts that have fewer HHAs as compared to the variation in benchmark values for the cohorts that have a greater number of HHAs.

We also performed a similar analysis with the achievement thresholds and comparing how the individual benchmarks and achievement thresholds would fluctuate from one year to the next for the smaller-volume cohorts, larger-volume cohorts, and the state level cohorts. The results of those analyses were similar.

Based on the analyses that we have described, we are concerned that if we separate HHAs into smaller- and larger-volume cohorts by state for purposes of calculating the benchmarks and achievement thresholds, HHAs in the smaller-volume cohorts could be required to meet performance standards that are greater than the level of performance that HHAs in the larger-volume cohorts would be required to achieve. For this reason, we are proposing to calculate the benchmarks and achievement thresholds at the state level rather than at the smaller- and larger-volume cohort level for all model years, beginning with CY 2016. This change will eliminate the increased variation caused by having few HHAs in the cohort but still takes into account that there will be some inter-state variation in the values due to state regulatory differences.

We seek public comments on this proposal.

2. The Payment Adjustment Methodology

We finalized in the CY 2016 HH PPS final rule that we would use a linear exchange function (LEF) to translate a competing HHA's TPS into a value-based payment adjustment percentage under the HHVBP Model (80 FR 68686). We also finalized that we would calculate the LEF separately for each smaller-volume cohort and larger-volume cohort. In addition, we finalized that if an HHA does not have a minimum of 20 episodes of care during a performance year to generate a performance score on at least five measures, we would not include the HHA in the LEF and we would not calculate a payment adjustment percentage for that HHA.

Since the publication of the CY 2016 HH PPS final rule, we have continued to evaluate the payment adjustment methodology using the most recent data available. We updated our analysis of the 10 OASIS quality measures and two claims-based measures using the newly available 2014 QIES Roll Up File data, which was not available prior to the issuance of that final rule.[19] We also determined the size of the cohorts using the 2014 Quality Episode File based on OASIS assessments rather than archived quality data sources that were used in the CY 2016 rule, whereby the HHAs reported at least five measures with over 20 episodes of care. Based on this data, we determined that with respect to performance year 2016, there were only three states (AZ, FL, NE) that have more than 10 HHAs in the smaller-volume cohort; one state (IA) that has 8–10 HHAs in the smaller-volume cohort, three states (NC, MA, TN) that have 1–3 HHAs in the smaller-volume cohort; and two states (MD, WA) that have no HHAs in the smaller-volume cohort. In the CY 2016 HH PPS final rule (80 FR 68664), we finalized that when there are too few HHAs in the smaller-volume cohort in each state to compete in a fair manner, the HHAs in that cohort would be included in the larger-volume cohort for purposes of calculating their payment adjustment percentage. The CY 2016 rule further defines too few as when there is only one or two HHAs competing within a smaller-volume cohort in a given state.

We also used the more current data source mentioned above to analyze the effects of outliers on the LEF. As indicated by the payment distributions set forth in Table 23 of this rule, the LEF is designed so that the majority of the payment adjustment values fall closer to the median and only a small percentage of HHAs receive adjustments at the higher and lower ends of the distribution. However, when we looked at the more recent data, we discovered that if there are only three or four HHAs in the cohort, one HHA outlier could skew the payment adjustments and deviate the payment distribution from the intended design of the LEF payment methodology where HHAs should fall close to the median of the payment distribution. For example, if there are only three HHAs in the cohort, we concluded that there is a high likelihood that those HHAs would have payment adjustments of −2.5 percent, −2.0 percent and +4.5 percent when the maximum payment adjustment is 5 percent, none falling close to the mean, with the result that those HHAs would receive payment adjustments at the higher or lower ends of the distribution. As the size of the cohort increases, we determined that this became less of an issue, and that the majority of the HHAs would have payment adjustments that are close to the median. This is illustrated in the payment distribution in Table 23 of this rule. Under the payment distribution for the larger-volume cohorts, 80 percent of the HHAs in AZ, IA, FL and NE would receive a payment adjustment ranging from −2.2 percent to +2.2 percent when the maximum payment adjustment is 5 percent (See state level cohort in Table 23). Arizona is a state that has a smaller-volume cohort with only nine HHAs but its payment distribution is comparable, ranging from −1 percent to +1 percent even with one outlier that is at 5 percent.

In order to determine the minimum number of HHAs that would have to be in a smaller-volume cohort in order to insulate that cohort from the effect of outliers, we analyzed performance results related to the OASIS and claims-based measures, as well as HHCAHPS, using 2013 and 2014 data. We specifically simulated the impact that outliers would have on cohort sizes ranging from four HHAs to twelve HHAs. We found that the LEF was less susceptible to large variation from outlier impacts once the cohort size reached a minimum of eight HHAs. We also found that a minimum of eight HHAs would allow for four states with smaller-volume cohorts to have 80 percent of their payment adjustments fall between −2.3 percent and + 2.4 percent. As a result of this analysis, we are proposing that a smaller-volume cohort have a minimum eight HHAs in order for the HHAs in that cohort to be compared only against each other, and not against the HHAs in the larger-volume cohort. We believe this proposal would better mitigate the impact of outliers as compared to our current policy, while also enabling us to evaluate the impact of the Model on competition between smaller-volume HHAs.

We are also proposing that if a smaller-volume cohort in a state has fewer than eight HHAs, those HHAs would be included in the larger-volume cohort for that state for purposes of calculating the LEF and payment adjustment percentages. If finalized, this change would apply to the CY 2018 payment adjustments and thereafter. We will continue to analyze and review the most current cohort size data as it becomes available. We seek public comments on this proposal.

C. Quality Measure Proposals

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 New Measures (80 FR 68671–68673) for the HHVBP Model to be used in the first performance year (PY1), referred to as the "starter set".

The measures were selected for the Model using the following guiding principles: (1) Use a broad measure set that captures the complexity of the services HHAs provide; (2) Incorporate the flexibility for future inclusion of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 measures that cut across post-acute care settings; (3) Develop 'second generation' (of the HHVBP Model) measures of patient outcomes, health and functional status, shared decision making, and patient activation; (4) Include a balance of process, outcome and patient experience measures; (5) Advance the ability to measure cost and value; (6) Add measures for appropriateness or overuse; and (7) Promote infrastructure investments. This set of quality measures encompasses the multiple National Quality Strategy (NQS) domains[20] (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care, (2) Care coordination, (3) Population & community health, (4) Person- and Caregiver-centered experience and outcomes, (5) Safety, and (6) Efficiency and cost reduction. Figures 5 and 6 of the CY 2016 HH PPS final rule identified 15 outcome measures (five from the HHCAHPS, eight from OASIS, and two from the Chronic Care Warehouse (claims)), and nine process measures (six from OASIS, and three New Measures, which were not previously reported in the home health setting).

During implementation of the Model, we determined that four of the measures finalized for PY1 require further consideration before inclusion in the HHVBP Model measure set as described below. Specifically, we are proposing to remove the following measures, as described in Figure 4a of the CY 2016 HH PPS final rule, from the set of applicable measures: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between

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[19] We did not update our analysis of the HHCAHPS measures because more recent data was not available.

[20] 2015 Annual Report to Congress, *http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm.*

October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received. We are proposing to remove these four measures, for the reasons discussed below, beginning with the CY 2016 Performance Year (PY1) calculations, and believe this will not cause substantial change in the first annual payment adjustment that will occur in CY 2018, as each measure is equally weighted and will not be represented in the calculations. The proposed revisions to the measure set, as set forth in Table 31 would be applicable to each performance year subject to any changes made through future rulemaking.

We are proposing to remove the "Care Management: Types and Sources of Assistance" measure because (1) a numerator and denominator for the measure were not made available in the CY2016 HH PPS final rule; and (2) the potential OASIS items that could be utilized in the development of the measure were not fully specified in the CY 2016 HH PPS final rule. We want to further consider the appropriate numerator and denominator for the OASIS data source before proposing the inclusion of this measure in the HHVBP Model.

We are proposing to remove the "Prior Functioning ADL/IADL" measure because (1) the NQF endorsed measure (NQF0430) included in the 2016 HH PPS final rule does not apply to home health agencies; and (2) the NQF endorsed measure (NQF0430) refers to a measure that utilizes the AM–PAC (Activity Measure for Post-Acute Care) tool that is not currently (and has never been) collected by home health agencies.

We are proposing to remove the "Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?" measure because this datum element (OASIS item M1041) is used to calculate another HHVBP measure "Influenza Immunization Received for Current Flu Season" and was not designed as an additional and separate measure of performance.

We are proposing to remove the "Reason Pneumococcal Vaccine Not Received" measure because (1) these data are reported as an element of the record for clinical decision making and inform agency policy (that is, so that the agency knows what proportion of its patients did not receive the vaccine because it was contraindicated (harmful) for the patient or that the patient chose to not receive the vaccine); and (2) this measure itemizes the reason for the removal of individuals for whom the vaccine is not appropriate, which is already included in the numerator of the "Pneumococcal Polysaccharide Vaccine Ever Received" measure also included in the HHVBP Model.

Because the starter set is defined as the quality measures selected for the first year of the Model only, we propose to revise § 484.315 to refer to "a set of quality measures" rather than "a starter set of quality measures" and to revise § 484.320 (a), (b), (c), and (d) to remove the phrase "in the starter set". We are also proposing to delete the definition of "Starter set" in § 484.305 because that definition would no longer be used in the HHVBP Model regulations following the proposed revisions to §§ 484.315 and 484.320.

The proposed revised set of applicable measures is presented in Table 31, which excludes the four measures we propose to be removed. We propose that this measure set will be applicable to PY1 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking. Moving forward, we plan to utilize an implementation contractor who will invite a group of measure experts to provide advice on the adjustment of the current measure set.

Table 31—Proposed Measure Set for the HHVBP Model[21]

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care	Improvement in Ambulation-Locomotion.	Outcome	NQF0167	OASIS (M1860)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in ambulation/locomotion at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Improvement in Bed Transferring.	Outcome	NQF0175	OASIS (M1850)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bed transferring at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Improvement in Bathing	Outcome	NQF0174	OASIS (M1830)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bathing at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Improvement in Dyspnea	Outcome	NA	OASIS (M1400)	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.

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[21] For more detailed information on the proposed measures utilizing OASIS refer to the *OASIS–C1/ICD–9, Changed Items & Data Collection Resources* dated September 3, 2014 available at *www.oasisanswers.com/LiteratureRetrieve.aspx?ID=215074.*

For NQF endorsed measures see The NQF Quality Positioning System available at *http://www.qualityforum.org/QPS.* For non-NQF measures using OASIS see links for data tables related to OASIS measures at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.* For information on HHCAHPS measures see *https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx.*

TABLE 31—PROPOSED MEASURE SET FOR THE HHVBP MODEL[21]—Continued

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Communication & Care Coordination.	Discharged to Community	Outcome	NA	OASIS (M2420)	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Efficiency & Cost Reduction	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health.	Outcome	NQF0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Efficiency & Cost Reduction	Emergency Department Use without Hospitalization.	Outcome	NQF0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Patient Safety	Improvement in Pain Interfering with Activity.	Outcome	NQF0177	OASIS (M1242)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient Safety	Improvement in Management of Oral Medications.	Outcome	NQF0176	OASIS (M2020)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health	Influenza Immunization Received for Current Flu Season.	Process	NQF0522	OASIS (M1046)	Number of home health episodes during which patients (a) received vaccination from the HHA or (b) had received vaccination from HHA during earlier episode of care, or (c) was determined to have received vaccination from another provider.	Number of home health episodes of care ending with discharge, or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health	Pneumococcal Polysaccharide Vaccine Ever Received.	Process	NQF0525	OASIS (M1051)	Number of home health episodes during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care	Drug Education on All Medications Provided to Patient/Caregiver during all Episodes of Care.	Process	NA	OASIS (M2015)	Number of home health episodes of care during which patient/caregiver was instructed on how to monitor the effectiveness of drug therapy, how to recognize potential adverse effects, and how and when to report problems (since the previous OASIS assessment).	Number of home health episodes of care ending with a discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient & Caregiver-Centered Experience.	Care of Patients	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Communications between Providers and Patients.	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Specific Care Issues	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Overall rating of home health care.	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Willingness to recommend the agency.	Outcome		CAHPS	NA	NA.

TABLE 31—PROPOSED MEASURE SET FOR THE HHVBP MODEL [21]—Continued

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Population/Community Health	Influenza Vaccination Coverage for Home Health Care Personnel.	Process	NQF0431 (Used in other care settings, not Home Health).	Reported by HHAs through Web Portal.	Healthcare personnel in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: (a) received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere: or (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other components of the vaccine or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; or (c) declined influenza vaccination; or (d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories.	Number of healthcare personnel who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.
Population/Community Health	Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?.	Process	NA	Reported by HHAs through Web Portal.	Total number of Medicare beneficiaries aged 60 years and over who report having ever received zoster vaccine (shingles vaccine).	Total number of Medicare beneficiaries aged 60 years and over receiving services from the HHA.
Communication & Care Coordination.	Advance Care Plan	Process	NQF0326	Reported by HHAs through Web Portal.	Patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	All patients aged 65 years and older.

In the CY 2016 HH PPS final rule, we finalized that HHAs will be required to begin reporting data on each of the three New Measures no later than October 7, 2016 for the period July 2016 through September 2016 and quarterly thereafter. We now propose to require annual, rather than quarterly reporting for one of the three New Measures, "Influenza Vaccination Coverage for Home Health Personnel," with the first annual submission in April 2017 for PY2. Specifically, we are proposing to require an annual submission in April for the prior 6-month reporting period of October 1–March 31 to coincide with the flu season. Under this proposal, for PY1, the HHA would report on this measure in October 2016 and January 2017. HHAs would report on this measure in April 2017 for PY2 and annually in April thereafter. We believe that changing the reporting and submission periods for this measure from quarterly to annually would avoid the need for HHAs to have to report zeroes in multiple data fields for the two quarters (July through September, and April through June) that fall outside of the parameters of the denominator (October through March).

We are not proposing to change the quarterly reporting and submission requirements as set forth in the CY 2016 HH PPS final rule (80 FR 68674–68678) for the other two New Measures, "Advanced Care Planning", and "Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?"

We are also proposing to increase the timeframe for submitting New Measures data from seven calendar days (80 FR 68675–68678) to fifteen calendar days following the end of each reporting period to account for weekends and holidays.

We invite public comment on our proposals.

D. Appeals Process Proposal

In the CY 2016 HH PPS final rule (80 FR 68689), we stated that we intended to propose an appeals mechanism in future rulemaking prior to the application of the first payment adjustments scheduled for CY 2018. We are proposing an appeals process for the HHVBP Model which includes the period to review and request recalculation of both the Interim Performance Reports and the Annual TPS and Payment Adjustment Reports, as finalized in the CY 2016 HH PPS final rule (80 FR 68688–68689) and subject to the modifications we are proposing here, and reconsideration request process for the Annual TPS and Payment Adjustment Report only, as described later in this section, which may only occur after an HHA has first submitted a recalculation request for the Annual TPS and Payment Adjustment Report.

As finalized in the CY 2016 HH PPS final rule, HHAs have the opportunity to review their Interim Performance Report following each quarterly posting. The Interim Performance Reports are posted on the HHVBP Secure Portal quarterly, setting forth the HHA's measure scores based on available data to date. The first Interim Performance Report will be provided to all competing HHAs in July 2016 and will include performance scores for the OASIS-based measures for the first quarter of CY 2016. See Table 32 for data provided in each report. The quarterly Interim Performance Reports will provide competing HHAs with the opportunity to identify and correct calculation errors and resolve discrepancies, thereby minimizing challenges to the annual performance scores linked to payment adjustment.

Competing HHAs also have the opportunity to review their Annual TPS and Payment Adjustment Report. We will inform each competing HHA of its TPS and payment adjustment percentage in an Annual TPS and Payment Adjustment Report provided prior to the calendar year for which the payment adjustment will be applied. The annual TPS will be calculated based on the calculation of performance measures contained in the Interim Performance Reports that have already been received by the HHAs for the performance year.

We are proposing specific timeframes for the submission of recalculation and reconsideration requests to ensure that the final payment adjustment percentage for each competing Medicare-certified HHA can be submitted to the Fiscal Intermediary Shared Systems in time to allow for application of the payment adjustments beginning in January of the following calendar year. We believe HHVBP payment adjustments should be timely and that the appeals process should be designed so that determinations on recalculations and reconsiderations can be made in advance of the applicable payment year to reduce burden and uncertainty for competing HHAs.

In this proposed rule, we are proposing to add new § 484.335, titled "Appeals Process for the Home Health Value-Based Purchasing Model," which would codify the recalculation request process finalized in the CY 2016 HH PPS final rule and also a proposed reconsideration request process for the Annual TPS and Payment Adjustment Report. The first level of this appeals process would be the recalculation request process, as finalized in the CY 2016 HH PPS final rule and subject to the proposed modifications described later in this section. We are proposing that the reconsideration request process for the Annual TPS and Payment Adjustment Report would complete the appeals process, and would be available only when an HHA has first submitted a recalculation request for the Annual TPS and Payment Adjustment Report under the process finalized in the CY 2016 HH PPS final rule, subject to the modifications we are proposing here. We believe that this proposed appeals process will allow the HHAs to seek timely corrections for errors that may be introduced during the Interim Performance Reports that could affect an HHA's payments.

To inform our proposal for an appeals process under the HHVBP Model we reviewed the appeals policies for two CMS programs that are similar in their program goals to the HHVBP Model, the Medicare Shared Savings Program [22] and Hospital Value-Based Purchasing Program,[23] as well as the appeals policy for the Comprehensive Care for Joint Replacement Model [24] that is being tested by the Center for Medicare and Medicaid Innovation (CMMI).

Under section 1115A(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites or participants to test those models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act.
- Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in section 1115A(c)(1) or (2) of the Act.

TABLE 32—HHVBP MODEL PERFORMANCE REPORT DATA SCHEDULE

Report type	Publication date	OASIS-Based measures and new measures	Claims- and HHCAHPS-based measures
Interim Performance Scores	January	3 quarters of previous PY (9 months); [Jan–Sept].	2 quarters of previous PY (6 months); [Jan–Jun].
Interim Performance Scores	April	12 months of previous PY [Jan–Dec]	3 quarters of previous PY (9 months); [Jan–Sept].
Interim Performance Scores	July	1st quarter of next PY (3 months); [Jan–Mar].	12 months of previous PY; [Jan–Dec].
Interim Performance Scores	October	2 quarters of next PY (6 months); [Jan–Jun].	1st quarter of next PY (3 months); [Jan–Mar].
Annual TPS and Payment Adjustment Percentage.	August	Entire 12 months of previous PY; [Jan–Dec].	
Annual TPS and Payment Adjustment Percentage; (Final).	November	Entire 12 months of previous PY [Jan–Dec] after all recalculations and reconsideration requests processed.	

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[22] Title 42—Public Health, Chapter IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B, Part 425—Medicare Shared Savings Program, Subpart I—Reconsideration Review Process. (*http://www.ecfr.gov/cgi-bin/text-idx?SID=880f6bd181904fc648f0e9a885103dba&mc=true&node=sp42.3.425.i&rgn=div6*)

[23] Title 42—Public Health, Chapter IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B, Part 412—Prospective Payment System for Inpatient Hospital Services, Subpart I—Adjustments to the Base Operating DRG Payment Amounts Under the Prospective Payment Systems for Inpatient Operating Costs (*http://www.ecfr.gov/cgi-bin/text-idx?SID=dd15db0a13792035b9b42b342270fad6&mc=true&node=sg42.2.412_1155_6412_1159.sg4&rgn=div7*)

[24] Title 42—Public Health, Chapter IV—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter H—Health Care Infrastructure and Model Programs, Part 510—Comprehensive Care for Joint Replacement Model. (*http://www.ecfr.gov/cgi-bin/text-idx?SID=a18d6f5665d1fbf2e1ae955e1bf1b97c&mc=true&node=pt42.5.510&rgn=div5*)

1. Recalculation

HHAs may submit recalculation requests for both the Interim Performance Reports and the Annual TPS and Payment Adjustment Report via a form located on the HHVBP Secure Portal that is only accessible to the competing HHAs. The request form would be entered by a person who has legal authority to sign on behalf of the HHA and, as finalized in the CY 2016 HH PPS final rule, must be submitted within 30 calendar days of the posting of each performance report on the model-specific Web site. For the reasons discussed later in this section, we are proposing to change this policy to require that recalculation requests for both the Interim Performance Report and the Annual TPS and Payment Adjustment Report be submitted within 15 calendar days of the posting of the Interim Performance Report and the Annual TPS and Payment Adjustment Report on the HHVBP Secure Portal instead of 30 calendar days.

For both the Interim Performance Reports and the Annual TPS and Payment Adjustment Report, requests for recalculation must contain specific information, as set forth in the CY 2016 HH PPS final rule (80 FR 68688). We are proposing that requests for reconsideration of the Annual TPS and Payment Adjustment Report must also contain this same information.

- The provider's name, address associated with the services delivered, and CMS Certification Number (CCN);
- The basis for requesting recalculation to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect;
- Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box); and,
- A copy of any supporting documentation the HHA wishes to submit in electronic form via the model-specific Web page.

Following receipt of a request for recalculation of an Interim Performance Report or the Annual TPS and Payment Adjustment Report, CMS or its agent will:

- Provide an email acknowledgement, using the contact information provided in the recalculation request, to the HHA contact notifying the HHA that the request has been received;
- Review the request to determine validity, and determine whether the recalculation request results in a score change, altering performance measure scores or the HHA's TPS;
- Conduct a review of quality data if recalculation results in a performance score or TPS change, and recalculate the TPS using the corrected performance data if an error is found; and,
- Provide a formal response to the HHA contact, using the contact information provided in the recalculation request, notifying the HHA of the outcome of the review and recalculation process.

We anticipate providing this response as soon as administratively feasible following the submission of the request.

We will not be responsible for providing HHAs with the underlying source data utilized to generate performance measure scores because HHAs have access to this data via the QIES system.

We are proposing that recalculation requests for the Interim Performance Reports must be submitted within 15 calendar days of these reports being posted on the HHVBP Secure Portal, rather than 30 calendar days as finalized in the CY 2016 HH PPS final rule. We believe this would allow recalculations of the Interim Performance Reports posted in July to be completed prior to the posting of the Annual TPS and Payment Adjustment Report in August. We are proposing that recalculation requests for the TPS or payment adjustment percentage must be submitted within 15 calendar days of the Annual TPS and Payment Adjustment Report being posted on the HHVBP Secure Portal, rather than 30 days as finalized in the CY 2016 HH PPS final rule. We are proposing to shorten this timeframe to allow for a second level of appeals, the proposed reconsideration request process, to be completed prior to the generation of the final data files containing the payment adjustment percentage for each competing Medicare-certified HHA and the submission of those data files to the Fiscal Intermediary Share Systems. We contemplated longer timeframes for the submission of both recalculation and reconsideration requests for the Annual TPS and Payment Adjustment Reports, but believe that this would result in appeals not being resolved in advance of the payment adjustments being applied beginning in January of the following calendar year. We invite comments on this proposed timeframe for recalculation requests, as well as any alternatives.

2. Reconsideration

We are proposing that if we determine that the calculation was correct and deny the HHA request for recalculation of the Annual TPS and Payment Adjustment Report, or if the HHA disagrees with the results of a CMS recalculation of such report, the HHA may submit a reconsideration request for the Annual TPS and Payment Adjustment Report. The reconsideration request and supporting documentation would be required to be submitted via the form on the HHVBP Secure Portal within 15 calendar days of CMS' notification to the HHA contact of the outcome of the recalculation request for the Annual TPS and Payment Adjustment Report.

We propose that an HHA may request reconsideration of the outcome of a recalculation request for its Annual TPS and Payment Adjustment Report only. We believe that the ability to review the Interim Performance Reports and submit recalculation requests on a quarterly basis provides competing HHAs with a mechanism to address potential errors in advance of receiving their annual TPS and payment adjustment percentage. Therefore, we expect that in many cases, the reconsideration request process proposed in this rule would result in a mechanical review of the application of the formulas for the TPS and the LEF, which could result in the determination that a formula was not accurately applied. Reconsiderations would be conducted by a CMS official who was not involved with the original recalculation request.

We are proposing that an HHA must submit the reconsideration request and supporting documentation via the HHVBP Secure Portal within 15 calendar days of CMS' notification to the HHA contact of the outcome of the recalculation process so that a decision on the reconsideration can be made prior to the generation of the final data files containing the payment adjustment percentage for each competing Medicare-certified HHA and the submission of those data files to the Fiscal Intermediary Share Systems. We believe that this would allow for finalization of the interim performance scores, TPS, and annual payment adjustment percentages in advance of the application of the payment adjustments for the applicable performance year. As noted above, we contemplated longer timeframes for the submission of both recalculation and reconsideration requests, but believe this would result in appeals not being resolved in advance of the payment adjustments being applied beginning in January of the following calendar year. CMS invites comments on its proposed timeframe for reconsideration requests, as well as any alternatives.

We finalized in the CY 2016 HH PPS final rule (80 FR 68688) that the final TPS and payment adjustment percentage would be provided to competing HHAs in a final report no later than 60 calendar days in advance of the payment adjustment taking effect. We are now proposing that the final TPS and payment adjustment percentage be provided to competing HHAs in a final report no later than 30 calendar days in advance of the payment adjustment taking effect to account for unforeseen delays that could occur between the time the Annual TPS and Payment Adjustment Reports are posted and the appeals process is completed.

We solicit comments on our proposals related to the appeals process for the HHVBP Model described in this section and the associated proposed regulation text at § 484.335.

E. Public Display of Total Performance Scores for the HHVBP Model

In the CY 2016 HH PPS final rule (80 FR 68658), we stated that one of the three goals of the HHVBP Model is to "Enhance current public reporting processes". Annual publicly-available performance reports would be a means of developing greater transparency of Medicare data on quality and aligning the competitive forces within the market to deliver care based on value over volume. The publicly-reported reports will inform home health industry stakeholders (consumers, physicians, hospitals) as well as all competing HHAs delivering care to Medicare beneficiaries within selected state boundaries on their level of quality relative to both their peers and their own past performance. These public reports would provide home health industry stakeholders, including providers and suppliers that refer their patients to HHAs, an opportunity to confirm that the beneficiaries they are referring for home health services are being provided the best possible quality of care available.

We received support via public comments to publicly report the HHVBP Model performance data because they would inform industry stakeholders of quality improvements. These comments noted several areas of value in performance data. Specifically, commenters suggested that public reports would permit providers to direct patients to a source of information about higher-performing HHAs based on quality reports. Commenters offered that to the extent possible, accurate comparable data will encourage HHAs to improve care delivery and patient outcomes, while better predicting and managing quality performance and payment updates. Although competing HHAs have direct technical support and other tools to encourage best practices, we believe public reporting of their Total Performance Score will encourage providers and patients to utilize this information when selecting a HHA to provide quality care.

We have employed a variety of means to ensure that we maintain transparency while developing and implementing the HHVBP Model. This same care is being taken as we plan public reporting in collaboration with other CMS components that use many of the same quality measures. We continue to engage and inform stakeholders about various aspects of the HHVBP Model through CMS Open Door Forums and updates to the HHVBP Model Innovation Center Web page (*https://innovation.cms.gov/initiatives/home-health-value-based-purchasing-model*). We have held several webinars since December 2015 to educate competing HHAs. Topics of the webinars ranged from an overview of the HHVBP Model to specific content areas addressed in the CY 2016 HH PPS final rule. The primary purpose of the focused attention provided to the competing HHAs through the HHVBP learning systems and webinars is to facilitate direct communication, sharing of information, and collaboration.

Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit patient-level quality of care data using the Outcome and Information Assessment Set (OASIS) and the Home Health Consumer Assessment of Health Care Providers and Systems (HHCAHPS). Section 1895(b)(3)(B)(v)(III) of the Act states that this quality data is to be made available to the public. Thus, home health agencies have been required to collect OASIS data since 1999 and report HHCAHPS data since 2012. Use of OASIS measures for the HHVBP Model logically follows, as the validation through experience creates greater efficiency than constructing an entirely new set of measures.

We are considering various public reporting platforms for the HHVBP Model including Home Health Compare (HHC) and the Center for Medicare and Medicaid Innovation (CMMI) Web page as a vehicle for maintaining information in a centralized location and making information available over the Internet. We believe the public reporting of competing HHAs' performance scores under the HHVBP Model supports our continuing efforts to empower consumers by providing more information to help them make health care decisions, while also encouraging providers to strive for higher levels of quality. As the public reporting mechanism for the HHVBP Model is being developed, we are considering which data elements reported will be meaningful to stakeholders and may inform the selection of HHAs for care.

We are considering public reporting for the HHVBP Model, beginning no earlier than CY 2019, to allow analysis of at least eight quarters of performance data for the Model and the opportunity to compare how those results align with other publicly reported quality data. We are encouraged by the previous stakeholder comments and support for public reporting that could assist patients, physicians, discharge planners, and other referral sources to choose higher-performing HHAs.

V. Proposed Updates to the Home Health Care Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the Act requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary is directed to reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage for a particular year, the 2 percentage point reduction under section 1895(b)(3)(B)(v)(I) of the Act may result in this percentage increase, after application of the productivity adjustment under section 1895(b)(3)(B)(vi)(I) of the Act, being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) imposed new data reporting requirements for certain post-acute care (PAC) providers, including HHAs. For more information on the statutory background of the IMPACT Act, please refer to the CY 2016 HH PPS final rule (80 FR 68690 through 68692).

In that final rule, we established our approach for identifying cross-setting measures and processes for the adoption of measures, including the application and purpose of the Measures Application Partnership (MAP) and the notice and comment rulemaking process. More information on the

IMPACT Act is also available at *https://www.govtrack.us/congress/bills/113/hr4994.*

In the CY 2016 HH PPS final rule (80 FR 68692), we also discussed the reporting of OASIS data as it relates to the implementation of ICD–10 on October 1, 2015. We submitted a new request for approval to OMB for the OASIS–C1/ICD–10 version under the Paperwork Reduction Act (PRA) process, including a new OMB control number (*see* 80 FR 15796). The new information collection request for OASIS–C1/ICD–10 version was approved under OMB control number 0938–1279 with a current expiration date of May 31, 2018. To satisfy requirements in the IMPACT Act that HHAs submit standardized patient assessment data in accordance with section 1899B(b) and to create consistency in the lookback period across selected OASIS items, we have created a modified version of the OASIS, OASIS–C2. We have submitted request for approval to OMB for the OASIS–C2 version under the PRA process (81 FR 18855); also see *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.* The OASIS–C2 version will replace the OASIS–C1/ICD–10 and will be effective for data collected with an assessment completion date (M0090) on and after January 1, 2017. Information regarding the OASIS–C1/ICD–10 and C2 can be located on the OASIS Data Sets Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html.*

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

We refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68698) for a detailed discussion of the considerations we apply in measure selection for the Home Health Quality Reporting Program (HH QRP), such as alignment with the CMS Quality Strategy,[25] which incorporates the three broad aims of the National Quality Strategy.[26] Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. Quality reporting programs (QRPs), coupled with public reporting of quality information are critical to the advancement of health care quality improvement efforts. Valid, reliable, and relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for us in all of our QRPs.

In this proposed rule, we propose to adopt for the HH QRP one measure that we are specifying under section 1899B(c)(1)(C) of the Act to meet the Medication Reconciliation domain: (1) Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post-Acute Care Home Health Quality Reporting Program (Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP). Further, we are proposing to adopt for the HH QRP three measures to meet the "Resource Use and other Measures" domains required by section 1899B(d)(1) of the Act: (1) Total Estimated Medicare Spending per Beneficiary—Post Acute Care Home Health Quality Reporting Program (MSPB–PAC HH QRP); (2) Discharge to Community—Post Acute Care Home Health Quality Reporting Program (Discharge to Community-PAC HH QRP); and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for Post-Acute Care Home Health Quality Reporting Program (Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP).

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015 for the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community-PAC HH QRP; on August 12–13, 2015, and October 14, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP; and on October 29–30, 2015, for the MSPB–PAC HH QRP measures. In addition, we released draft quality measure specifications for public comment on the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP from September 18, 2015 to October 6, 2015, for the Discharge to Community-PAC HH QRP from November 9, 2015 to December 8, 2015, for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP from November 2, 2015 to December 1, 2015, and for the MSPB–PAC HH QRP measures from January 13, 2016 to February 5, 2016. Further, we opened a public mailbox, *PACQualityInitiative@cms.hhs.gov,* for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site, on the IMPACT Act of 2014 Data Standardization & Cross Setting Measures Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-MeasuresMeasures.html.*

Additionally, we sought public input from the MAP Post-Acute Care, Long-Term Care Workgroup during the annual public meeting held December 14–15, 2015. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act, tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act. The MAP reviewed each measure proposed in this rule for use in the HH QRP. For more information on the MAP, we refer readers to the CY 2016 HH PPS final rule (80 FR 68692 through 68694). Further, for more information on the MAP's recommendations, we refer readers to the MAP 2015–2016 Considerations for Implementing Measures in Federal Programs public report at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the HH QRP, we are proposing measures for the HH QRP for the purposes of satisfying the measure domains required under the IMPACT Act measures that most closely align with the national priorities identified in the National Quality Strategy (*http://www.ahrq.gov/workingforquality/*) and with respect to which the MAP supports the measure concept. Further, we discuss below the importance and high-priority status of these proposed measures in the HH setting.

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[25] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[26] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

C. Process for Retaining, Removing, and Replacing Previously Adopted Home Health Quality Reporting Program Measures for Subsequent Payment Determinations

Consistent with the policies of other provider QRPs, including the Hospital Inpatient Quality Reporting Program (Hospital IQR) (77 FR 53512 through 53513), the Hospital Outpatient Quality Reporting Program (Hospital OQR) (77 FR 68471), the LTCH QRP (77 FR 53614 through 53615), and the IRF QRP (77 FR 68500 through 68507), we are proposing that when we initially adopt a measure for the HH QRP for a payment determination, this measure will be automatically retained for all subsequent payment determinations unless we propose to remove or replace the measure, or unless the exception discussed below applies.

We are proposing to define the term "remove" to mean that the measure is no longer a part of the HH QRP measure set, data on the measure will no longer be collected for purposes of the HH QRP, and the performance data for the measure will no longer be displayed on HH Compare. We are also proposing to use the following criteria when considering a quality measure for removal: (1) Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; and (6) a measure that is more strongly associated with desired patient outcomes for the particular topic is available. These items may still appear on OASIS for previously established purposes that are non-related to our HH QRP. HHAs will be able to access these reports using the Certification and Survey Provider Enhanced Reports (CASPER) system and can use the information for their own monitoring and quality improvement efforts.

Further, we are proposing to define "replace" to mean that we would adopt a different quality measure in place of a currently used quality measure, for one or more of the reasons described above. Additionally, we are proposing that any such "removal" or "replacement" will take place through notice-and-comment rulemaking, unless we determine that a measure is causing concern for patient safety. Specifically, in the case of a HH QRP measure for which there is a reason to believe that the continued collection raises possible safety concerns or would cause other unintended consequences, we propose to promptly remove the measure and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle. In addition, we will immediately notify HHAs and the public through the usual communication channels, including listening session, memos, email notification, and Web postings. If we removed a measure under these circumstances, we would also not continue to collect data on that measure under our alternative authorities for purposes other than the HH QRP.

We invite public comment on our proposed policy for retaining, removing and replacing previously adopted quality measures, including the criteria we propose to use when considering whether to remove a quality measure from the HH QRP.

D. Quality Measures That Will Be Removed From the Home Health Quality Initiative, and Quality Measures That Are Proposed for Removal From the HH QRP Beginning With the CY 2018 Payment Determination

In 2015, we undertook a comprehensive reevaluation of all 81 HH quality measures, some of which are used only in the Home Health Quality Initiative (HHQI), and others which are also used in the HH QRP. This review of all the measures was performed in accordance with the guidelines from the CMS Measure Management System (MMS) (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint.html*). The goal of this reevaluation was to streamline the measure set, consistent with MMS guidance and in response to stakeholder feedback. This reevaluation included a review of the current scientific basis for each measure, clinical relevance, usability for quality improvement, and evaluation of measure properties, including reportability, and variability. Our measure development and maintenance contractor convened a Technical Expert Panel (TEP) on August 21, 2015, to review and advise on the reevaluation results. The TEP provided feedback on which measures are most useful for patients, caregivers, clinicians, and stakeholders, and on analytics and an environmental scan conducted to inform measure set revisions. Further information about the TEP feedback is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Health-Quality-Reporting-Program-HHQRP-TEP-.zip.*

As a result of the comprehensive reevaluation described above, we identified 28 HHQI measures that were either "topped out" and/or determined to be of limited clinical and quality improvement value by TEP members. Therefore, these measures will no longer be included in the HHQI. A list of these measures, along with our reasons for no longer including them in the HHQI, can be found at the following link *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

In addition, based on the results of the comprehensive reevaluation and the TEP input, we are proposing to remove 6 process measures from the HH QRP, beginning with the CY 2018 payment determination, because they are "topped out" and therefore no longer have sufficient variability to distinguish between providers in public reporting. These 6 measures are different than the 28 measures that will no longer be included within the HHQI. If this proposal is finalized, items used to calculate one or more of these six measures may still appear on the OASIS for previously established purposes that are not related to the HH QRP.

The 6 process measures we are proposing to remove from the HH QRP are:

- Pain Assessment Conducted;
- Pain Interventions Implemented During All Episodes of Care;
- Pressure Ulcer Risk Assessment Conducted;
- Pressure Ulcer Prevention in Plan of Care;
- Pressure Ulcer Prevention Implemented During All Episodes of Care; and
- Heart Failure Symptoms Addressed During All Episodes of Care.

The technical analysis that supports our proposal to remove the six process measures can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

We invite public comment on our above proposal to remove 6 process measures from the HH QRP.

E. Proposed Process for Adoption of Updates to HH QRP Measures

We believe that it is important to have in place a sub-regulatory process to incorporate non-substantive updates into the measure specifications so that these measures remain up-to-date. We also recognize that some changes are substantive in nature and might not be appropriate for adoption using a sub-regulatory process.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505), we finalized a policy for the Hospital IQR Program under which we use a subregulatory process to make nonsubstantive updates to measures used for that program. For what constitutes substantive versus nonsubstantive changes, we make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include: Updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure. Nonsubstantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. Examples of changes that we might consider to be substantive would be those in which: The changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change might be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice.

We are proposing to implement the same process for adopting updates to measures in the HH QRP, and would apply this process, including our policy for determining on a case-by-case basis whether an update is substantive or nonsubstantive. We believe this process adequately balances our need to incorporate updates to the HH QRP measures in the most expeditious manner possible while preserving the public's ability to comment on updates that do not fundamentally change a measure that it is no longer the same measure that we originally adopted.

We invite public comment on this proposal.

F. Modifications to Guidance Regarding Assessment Data Reporting in the OASIS

We are proposing modifications to our coding guidance modifications related to certain pressure ulcer items on the OASIS. In the CY 2016 HH PPS final rule (80 FR 68700), we adopted the NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) measure for use in the HH QRP for the CY 2018 HH QRP payment determination and subsequent years. Concurrent with the effective date for OASIS–C2 of January 1, 2017, we would use modified guidance for the reporting of current pressure ulcers. The purpose of this modification is to align with reporting guidance used in other post-acute care settings and with the policies of relevant clinical associations. Chapter 3 of the OASIS–C1/ICD–10 Guidance Manual currently states "Stage III and IV (full thickness) pressure ulcers heal through a process of contraction, granulation, and epithelialization. They can never be considered 'fully healed' but they can be considered closed when they are fully granulated and the wound surface is covered with new epithelial tissue." We utilize professional organizations, such as the National Pressure Ulcer Advisory Panel (NPUAP) to provide clinical insight and expertise related to the use and completion of relevant OASIS items. Based on the currently published position statements and best practices available from the NPUAP,[27] effective January 1, 2017, full-thickness (Stage 3 or 4) pressure ulcers should not be reported on OASIS as unhealed pressure ulcers once complete re-epithelialization has occurred. This represents a change in past guidance, and will allow OASIS data collection to conform to professional clinical guidelines, and align with pressure ulcer reporting practices in other post-acute care settings. In addition to revising guidance related to closed Stage 3 and 4 pressure ulcers, we are changing the reporting instructions when a graft is applied to a pressure ulcer. Current guidance states that when a graft is placed on a pressure ulcer, the wound remains a pressure ulcer and is not concurrently reported as a surgical wound on the OASIS. In order to align with reporting guidance in other post-acute care settings, effective January 1, 2017, once a graft is applied to a pressure ulcer, the wound will be reported on OASIS as a surgical wound, and no longer be reported as a pressure ulcer.

G. Proposed HH QRP Quality, Resource Use, and Other Measures for the CY 2018 Payment Determination and Subsequent Years

For the CY 2018 payment determination and subsequent years, in addition to the quality measures we would retain if our proposed policy on retaining measures is finalized, we are proposing to adopt four new measures. These four measures were developed to meet the requirements of the IMPACT Act. These proposed measures are:

- MSPB–PAC HH QRP;
- Discharge to Community-PAC HH QRP;
- Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP; and
- Drug Regimen Review Conducted With Follow-Up for Identified Issues-PAC HH QRP

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding agencies to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on agencies' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the resource use measures.

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[27] *http://www.npuap.org/wp-content/uploads/2012/01/Reverse-Staging-Position-Statement.pdf.*

1. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: MSPB–PAC HH QRP

Section 1899B(d)(1)(A) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is October 1, 2016 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify a measure to address the domain of resource use measures, including total estimated Medicare spending per beneficiary. We are proposing to adopt the measure, MSPB–PAC HH QRP, for which we would begin to collect data on January 1, 2017 for the CY 2018 payment determination and subsequent years as a Medicare fee-for-service (FFS) claims-based measure to meet this requirement.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an average annual rate of 6.1 percent and doubled to $59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.[28] A study commissioned by the Institute of Medicine found that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.[29]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. Therefore, we are proposing to adopt this MSPB–PAC HH QRP measure under section 1899B(e)(2)(B) of the Act, which allows us to specify a measure under section 1899B that is not NQF-endorsed if the measure deals with a specified area or medical topic the Secretary has determined to be appropriate for which there is no feasible or practical NQF-endorsed measure. We recognize that there are other measures that address Medicare spending per beneficiary, but we are not aware of any such measures that have been endorsed or adopted specifically for the home health setting. Given the current lack of resource use measures for PAC settings, our proposed MSPB–PAC HH QRP measure has the potential to provide valuable information to HHAs on their relative Medicare spending in delivering services to approximately 3.5 million Medicare beneficiaries.[30]

The proposed MSPB–PAC HH QRP episode-based measure would provide actionable and transparent information to support HHAs' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC HH QRP measure holds HHAs accountable for the Medicare payments within an "episode of care" (episode), which includes the period during which a patient is directly under the HHA's care, as well as a defined period after the end of the HHA treatment, which may be reflective of and influenced by the services furnished by the HHA. MSPB–PAC HH QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2014, Medicare FFS beneficiaries experienced 5,379,410 MSPB–PAC HH QRP episodes triggered by admission to a HHA. The mean payment-standardized, risk-adjusted episode spending for these episodes was $10,348 during that fiscal year. There was substantial variation in the Medicare payments for these MSPB–PAC HH QRP episodes—ranging from approximately $2,480 at the 5th percentile to approximately $31,964 at the 95th percentile. This variation was partially driven by variation in payments occurring following HH treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the MSPB–PAC measures and believe that measuring Medicare spending is critical for improving efficiency, others believe that resource use measures do not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, we believe that HHAs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination will perform well on this measure because beneficiaries will experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can recognize HHAs that are involved in the provision of high quality care at lower cost.

We have undertaken development of MSPB–PAC measures for each of the four PAC settings. In addition to this measure proposal, we proposed a LTCH-specific MSPB–PAC measure in the FY 2017 IPPS/LTCH proposed rule (81 FR 25216 through 25220), an IRF-specific MSPB–PAC measure in the FY 2017 IRF PPS proposed rule (81 FR 24197 through 24201), and a SNF-specific MSPB–PAC measure in the FY 2017 SNF PPS proposed rule (81 FR 24258 through 24262). These four setting-specific MSPB–PAC measures are closely aligned in terms of episode construction and measure calculation. Each of the MSPB–PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined similarly for each of the MSPB–PAC measures. However, developing setting-specific measures allows us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. For example, the MSPB–PAC HH QRP measure compares episodes triggered by Partial Episode Payment (PEP) and Low-Utilization Payment Adjustment (LUPA) claims only with episodes of the same type, as detailed below.

The MSPB–PAC measures mirror the general construction of the inpatient prospective payment system (IPPS) hospital MSPB measure, which was adopted for the Hospital IQR Program beginning with the FY 2014 program, and was implemented in the Hospital VBP Program beginning with the FY 2015 program. The measure was endorsed by the NQF on December 6, 2013 (NQF #2158).[31] The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which comprises the periods immediately prior to, during, and following a patient's hospital inpatient stay.[32] [33] Similarly, the MSPB–PAC measures assess all Medicare Part A and Part B payments for FFS claims with a start date that begins at the episode trigger and continues for the length of the episode window (which, as discussed in this section, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC HH QRP episode). However, there are differences between the MSPB–PAC measures, as proposed, and the hospital MSPB measure that reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB–PAC measures exclude a limited set of services (for example, for clinically unrelated services) provided to a beneficiary during the episode window while the hospital MSPB measure does not exclude any services.[34]

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[28] MedPAC, "A Data Book: Health Care Spending and the Medicare Program," (2015). 114.

[29] Institute of Medicine, "Variation in Health Care Spending: Target Decision Making, Not Geography," (Washington, DC: National Academies 2013). 2.

[30] Figures for 2013. MedPAC, "Medicare Payment Policy," Report to the Congress (2015). xvii–xviii.

[31] QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[32] QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[33] FY 2012 IPPS/LTCH PPS final rule (76 FR 51619).

MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. A home health episode beginning within 30 days of discharge from an inpatient hospital will therefore be included: Once in the hospital's MSPB measure, and once in the HHA's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We have sought and considered the input of stakeholders throughout the measure development process for the MSPB–PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015, in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015, to which 7 responses were received by December 8, 2015. The MSPB–PAC TEP Summary Report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert-Panel-on-Medicare-Spending-Per-Beneficiary.pdf.* The measures were also presented to the MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB–PAC measures were under development, there were three voting options for members: Encourage continued development, do not encourage further consideration, and insufficient information.[35] The MAP PAC/LTC Workgroup voted to "encourage continued development" for each of the MSPB–PAC measures.[36] The MAP PAC/LTC Workgroup's vote of "encourage continued development" was affirmed by the MAP Coordinating Committee on January 26, 2016.[37] The MAP's concerns about the MSPB–PAC measures, as outlined in its final report, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care," and Spreadsheet of Final Recommendations were taken into consideration during our measure development process and are discussed as part of our responses to public comments we received during the measure development process, described below.[38] [39]

Since the MAP's review and recommendation of continued development, we have continued to refine the risk adjustment model and conduct measure testing for the proposed MSPB–PAC measures. The proposed MSPB–PAC measures are both consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was originally open from January 13 to 27, 2016 and twice extended to January 29 and February 5. A total of 45 comments on the MSPB–PAC measures were received during this 3.5 week period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.[40] The MSPB–PAC Public Comment Summary Report is available *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_03_24_mspb_pac_public_comment_summary_report.pdf* and contains the public comments. If finalized, the proposed MSPB–PAC HH QRP measure, along with the other MSPB–PAC measures, as applicable, will be submitted for NQF consideration of endorsement.

To calculate the MSPB–PAC HH QRP measure for each HHA, we first define the construction of the MSPB–PAC HH QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further in this section. More detailed specifications for the proposed MSPB–PAC measures, including the MSPB–PAC HH QRP measure in this proposed rule, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_04_06_mspb_pac_measure_specifications_for_rulemaking.pdf.*

a. Episode Construction

An MSPB–PAC HH QRP episode begins at the episode trigger, which is defined as the patient's admission to a HHA. This admitting HHA is the provider for whom the MSPB–PAC HH QRP measure is calculated (that is, the attributed provider). The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC HH QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, HHAs will not be required to report any additional data to CMS for calculation of this measure. Thus, there will be no additional data collection burden from the implementation of this measure.

Our proposed MSPB–PAC HH QRP episode construction methodology differentiates between episodes triggered by standard HH claims (for which there is no PEP or LUPA adjustment) and claims for which PEP and LUPA adjustments apply, reflecting the HHA PPS payment policy. Standard, PEP, and LUPA episodes would be compared only with standard, PEP and LUPA episodes, respectively. Differences in episode construction between these three episode types are noted below; they otherwise share the same definition.

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[34] FY 2012 IPPS/LTCH PPS final rule (76 FR 51620).

[35] National Quality Forum, Measure Applications Partnership, "Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016" (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693.*

[36] National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, "Meeting Transcript—Day 2 of 2" (December 15, 2015) 104–106 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470.*

[37] National Quality Forum, Measure Applications Partnership, "Meeting Transcript—Day 1 of 2" (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637.*

[38] National Quality Forum, Measure Applications Partnership, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care" Final Report, (February 2016) *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

[39] National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[40] National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

The episode window is comprised of a treatment period and an associated services period. For MSPB–PAC HH Standard and LUPA QRP episodes, the treatment period begins at the trigger (that is, on the first day of the home health claim) and ends after 60 days. For MSPB–PAC PEP QRP episodes, the treatment period begins at the trigger (that is, on the first day of the home health claim) and ends at discharge. The treatment period includes those services that are provided directly or reasonably managed by the HHA that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period. Certain services are excluded from the MSPB–PAC HH QRP episodes because they are clinically unrelated to HHA care, and/or because HHAs may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given HHA's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that have been determined by clinicians to be outside of the control of a HHA include: planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC HH QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC HH QRP episode in the 30 days post-treatment. One possible scenario occurs where a HHA discharges a beneficiary who is then admitted to a SNF within 30 days. The SNF claim would be included once as an associated service for the attributed provider of the first MSPB–PAC HH QRP episode and once as a treatment service for the attributed provider of the second MSPB–PAC SNF episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare. Even within the HH setting, one MSPB–PAC HH QRP episode may begin in the associated services period of another MSPB–PAC HH QRP episode in the 30 days post-treatment. The second HH claim would be included once as an associated service for the attributed HHA of the first MSPB–PAC HH QRP episode and once as a treatment service for the attributed HHA of the second MSPB–PAC HH QRP episode. Again, this ensures that HHAs have the same incentives throughout both MSPB–PAC HH QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC HH QRP episode were excluded from the second HHA's MSPB–PAC HH QRP measure, that HHA would not share the same incentives as the first HHA of the first MSPB–PAC HH QRP episode. The MSPB–PAC HH QRP measure is designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further below, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

b. Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC HH QRP episodes, defined according to the methodology previously discussed, are used to calculate the MSPB–PAC HH QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator. The measure calculation is performed separately for MSPB–PAC HH QRP standard, PEP, and LUPA episodes to ensure that they are compared only to other standard, PEP, and LUPA episodes, respectively. The final MSPB–PAC HH QRP measure would combine the three ratios above to construct one HHA score as described below.

(1) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC HH QRP measure to ensure that the MSPB–PAC HH QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between HHAs. The proposed episode-level exclusions are as follows:

- Any episode that is triggered by a HH claim outside the 50 states, DC, Puerto Rico, and U.S. territories.
- Any episode where the claim(s) constituting the attributed HHA provider's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed HHA provider's treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(2) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the MSPB–PAC HH QRP measure are payment-standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We propose to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).[41]

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed HHA. To assist with risk adjustment for MSPB–PAC HH QRP episodes, we create mutually exclusive and exhaustive clinical case mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC HH QRP episode. The beneficiaries in these clinical case mix categories have a greater degree of clinical similarity than the overall HHA patient population, and allow us to more accurately estimate Medicare spending. Our proposed MSPB–PAC HH QRP model, adapted for the HH setting from the NQF-endorsed hospital MSPB measure, uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. During the public comment period that ran from January 13 to February 5, 2016 discussed above, we sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC HH QRP episode window. Given the comments received, we propose to include the Medicare spending for hospice services but risk adjust for them, such that MSPB–PAC HH QRP episodes with hospice are compared to a benchmark reflecting other MSPB–PAC HH QRP episodes with hospice. We believe that this provides a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

As noted previously, we understand the important role that sociodemographic status, beyond age, plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as required under the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC HH QRP risk-adjustment model, we are not proposing to adjust the MSPB–PAC HH measure for socioeconomic and demographic factors at this time. As this MSPB–PAC HH QRP measure will be submitted to the NQF for consideration of endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic and demographic factors. We will monitor the results of the trial, studies, and recommendations. We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC HH QRP measure.

(3) Measure Numerator and Denominator

The MPSB–PAC HH QRP measure is a payment-standardized, risk-adjusted ratio that compares a given HHA's Medicare spending against the Medicare spending of other HHAs within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC HH QRP measure is calculated as the ratio of the MSPB–PAC Amount for each HHA divided by the episode-weighted median MSPB–PAC Amount across all HHAs. To calculate the MSPB–PAC Amount for each HHA, one calculates the average of the ratio of the standardized spending for HHA standard episodes over the expected spending (as predicted in risk adjustment) for HHA standard episodes, the average of the ratio of the standardized spending for HHA PEP episodes over the expected spending (as predicted in risk adjustment) for HHA PEP episodes, and the average of the ratio of the standardized spending for HHA LUPA episodes over the expected spending (as predicted in risk adjustment) for HHA LUPA episodes. This quantity is then multiplied by the average episode spending level across all HHAs nationally for standard, PEP, and LUPA episodes. The denominator for a HHA's MSPB–PAC HH QRP measure is the episode-weighted national median of the MSPB–PAC Amounts across all HHAs. An MSPB–PAC HH QRP measure of less than 1 indicates that a given HHA's Medicare spending is less than that of the national median HHA during a performance period. Mathematically, this is represented in equation (A) below:

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[41] QualityNet, "CMS Price (Payment) Standardization—Detailed Methods" (Revised May 2015) *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

$$(A)\mathit{MSPB\text{-}PAC\ HHA\ Measure}_j = \frac{\mathit{MSPB\text{-}PAC\ Amount}_j}{\mathit{National\ Median\ MSPB\text{-}PAC\ Amount}}$$

$$= \frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\widehat{Y_{ij}}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{\begin{gathered}\mathit{Episode\text{-}Weighted\ Median\ of}\\ \mathit{HHA\ Providers'\ MSPB\text{-}PAC\ Amount}\end{gathered}}$$

Where:

- Y_{ij} = attributed standardized spending for episode i and provider j
- $\hat{Y}_{ij}$ = expected standardized spending for episode i and provider j, as predicted from risk adjustment
- n_j = number of episodes for provider j
- n = total number of episodes nationally
- $i\in\{I_j\}$ = all episodes i in the set of episodes attributed to provider j.

a. Data Sources

The MSPB–PAC HH QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

b. Cohort

The measure cohort includes Medicare FFS beneficiaries with a HHA treatment period ending during the data collection period.

c. Reporting

If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2017. We are proposing a minimum of 20 episodes for reporting and inclusion in the HH QRP. For the reliability calculation, as described in the measure specifications provided above, we used data from FY 2014. The reliability results support the 20 episode case minimum, and 94.27 percent of HHAs had moderate or high reliability (above 0.4).

We invite public comment on our proposal to adopt the MSPB–PAC HH QRP measure for the HH QRP.

2. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care Home Health Quality Reporting Program

Section 1899B(d)(1)(B) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is October 1, 2016 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify a measure to address the domain of discharge to community. We are proposing to adopt the measure, Discharge to Community—PAC HH QRP for the HH QRP, beginning with the CY 2018 payment determination and subsequent years as a Medicare fee-for-service (FFS) claims-based measure to meet this requirement.

This proposed measure assesses successful discharge to the community from a HH setting, with successful discharge to the community including no unplanned hospitalizations and no deaths in the 31 days following discharge from the HH agency setting. Specifically, this proposed measure reports a HHA's risk-standardized rate of Medicare FFS patients who are discharged to the community following a HH episode, do not have an unplanned admission to an acute care hospital or LTCH in the 31 days following discharge to community, and remain alive during the 31 days following discharge to community. The term "community," for this measure, is defined as home/self-care, without home health services, based on Patient Discharge Status Codes 01 and 81 on the Medicare FFS claim.[42] [43] This measure is specified uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many patients who are not expected to make functional improvement during their HH episode and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[44] [45]

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode, compared with patients discharged to institutional settings.[46] [47] Given the high costs of care in institutional settings, encouraging post-acute providers to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.[48] Also, providers have discovered that successful discharge to the community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.[49] For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' out-of-pocket expenditures.[50]

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[42] Further description of patient discharge status codes can be found, for example, at the following Web page: *https://med.noridianmedicare.com/web/jea/topics/claim-submission/patient-status-codes*.

[43] This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of "community" for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504.

[44] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a post-acute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388–1393.

[45] Tanwir S, Montgomery K, Chari V, Nesathurai S. Stroke rehabilitation: Availability of a family member as caregiver and discharge destination. *European journal of physical and rehabilitation medicine.* 2014;50(3):355–362.

[46] Dobrez D, Heinemann AW, Deutsch A, Manheim L, Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2010;89(3):198–204.

[47] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System Final Report. RTI International;2009.

[48] Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Med Care. 2016 Mar;54(3):221–228.

[49] Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital:

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments associated with discharge from IRFs, SNFs, LTCHs, or HHAs to institutional settings, as compared with payments associated with discharge from these PAC providers to community settings.[51] Average, unadjusted Medicare payments associated with discharge to community settings ranged from $0 to $4,017 for IRF discharges; $0 to $3,544 for SNF discharges, $0 to $4,706 for LTCH discharges, and $0 to $992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from $11,847 to $25,364 for IRF discharges, $9,305 to $29,118 for SNF discharges, $12,465 to $18,205 for LTCH discharges, and $7,981 to $35,192 for HHA discharges.[52]

Measuring and comparing agency-level discharge to community rates is expected to help differentiate among agencies with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings, across a variety of facility-level characteristics such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), freestanding or hospital-based units, and across patient-level characteristics such as race and gender.[53] [54] [55] [56] [57] [58] In the HH Medicare FFS population, using CY 2013 national claims data, we found that approximately 82 percent of episodes ended with a discharge to the community. A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.[59] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[60] One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge[61] and a second study noted that between 58 percent and 63 percent of beneficiates were discharged to home with rates varying by admission site.[62] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[63]

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[64] [65] [66] [67] [68] Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.[69] [70] [71] [72] [73] The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care patients is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the proposed measure, Discharge to Community-PAC HH QRP into the HH QRP. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

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bundles in the real world. The Journal of arthroplasty. 2015;30(3):353–355.

[50] Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. Med Care. 2016 Jan 12. Epub ahead of print.

[51] Gage B, Morley M, Spain P, Ingber M. Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report. RTI International;2009.

[52] Ibid.

[53] Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. Archives of physical medicine and rehabilitation. 2014;95(1):29–38.

[54] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a post-acute geriatric rehabilitation unit. Archives of physical medicine and rehabilitation. 2000;81(10):1388–1393.

[55] March 2015 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission;2015.

[56] Bhandari VK, Kushel M, Price L, Schillinger D. Racial disparities in outcomes of inpatient stroke rehabilitation. Archives of physical medicine and rehabilitation. 2005;86(11):2081–2086.

[57] Chang PF, Ostir GV, Kuo YF, Granger CV, Ottenbacher KJ. Ethnic differences in discharge destination among older patients with traumatic brain injury. Archives of physical medicine and rehabilitation. 2008;89(2):231–236.

[58] Berges IM, Kuo YF, Ostir GV, Granger CV, Graham JE, Ottenbacher KJ. Gender and ethnic differences in rehabilitation outcomes after hip-replacement surgery. American journal of physical medicine & rehabilitation/Association of Academic Physiatrists. 2008;87(7):567–572.

[59] Scheinhorn DJ, Hassenpflug MS, Votto JJ, et al. Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study. Chest. 2007;131(1):85–93.

[60] Thakar CV, Quate-Operacz M, Leonard AC, Eckman MH. Outcomes of hemodialysis patients in a long-term care hospital setting: a single-center study. American journal of kidney diseases: the official journal of the National Kidney Foundation. 2010;55(2):300–306.

[61] Wolff JL, Meadow A, Weiss CO, Boyd CM, Leff B. Medicare home health patients' transitions through acute and post-acute care settings. Medical care. 2008;46(11):1188–1193.

[62] Riggs JS, Madigan EA. Describing Variation in Home Health Care Episodes for Patients with Heart Failure. Home Health Care Management & Practice 2012; 24(3) 146–152.

[63] Ibid.

[64] Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310–1318.

[65] Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442–448.

[66] Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130–1136.

[67] Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R: the journal of injury, function, and rehabilitation. 2015;7(4):354–364.

[68] Parker, E., Zimmerman, S., Rodriguez, S., & Lee, T. Exploring best practices in home health care: a review of available evidence on select innovations. Home Health Care Management and Practice, 2014; 26(1): 17–33.

[69] Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. Archives of physical medicine and rehabilitation. 2015;96(7):1310–1318.

[70] Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. Archives of physical medicine and rehabilitation. 2005;86(3):442–448.

[71] Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. Journal of the American Geriatrics Society. 2011;59(6):1130–1136.

[72] Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. PM & R: the journal of injury, function, and rehabilitation. 2015;7(4):354–364.

[73] Parker, E., Zimmerman, S., Rodriguez, S., & Lee, T. Exploring best practices in home health care: a review of available evidence on select innovations. Home Health Care Management and Practice, 2014; 26(1): 17–33.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015 through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the proposed measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed Discharge to Community-PAC HH QRP measure in the HH QRP. The MAP encouraged continued development of the proposed measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this proposed measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

Since the MAP review the measure and recommended continued development, we have continued to refine the risk adjustment model and conduct measure testing for this measure. This proposed measure is consistent with the information submitted to the MAP and is scientifically acceptable for current specification in the HH QRP.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to the community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the measure, Discharge to Community-PAC HH QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We are proposing to use data from the Medicare FFS claims and Medicare eligibility files to calculate this proposed measure. We are proposing to use data from the "Patient Discharge Status Code" on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this proposed measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the "Patient Discharge Status Code" on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the HH setting, using 2013 data, we found 97 percent agreement in discharge to community codes when comparing "Patient Discharge Status Code" from claims and Discharge Disposition (M2420) and Inpatient Facility (M2410) on the OASIS C discharge assessment, when the claims and OASIS assessment had the same discharge date. We further examined the accuracy of "Patient Discharge Status Code" on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We found that 50 percent of HH claims with acute care discharge status codes were followed by an acute care claim in the 31 days after HH discharge. We believe these data support the use of the "Patient Discharge Status Code" for determining discharge to a community setting for this measure. In addition, the proposed measure has high feasibility because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to us.

Based on the evidence discussed above, we are proposing to adopt the measure entitled, "Discharge to Community-PAC HH QRP", for the HH QRP for the CY 2018 payment determination and subsequent years. This proposed measure is calculated utilizing 2 years of data as defined below. We are proposing a minimum of 20 eligible episodes in a given HHA for public reporting of the proposed measure for that HHA. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, HHAs will not be required to report any additional data to CMS for calculation of this measure. The proposed measure denominator is the risk-adjusted expected number of discharges to community. The proposed measure numerator is the risk-adjusted estimate of the number of home health patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, and ESRD status among other variables. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we refer readers the document titled Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

If this proposed measure is finalized, we intend to provide initial confidential feedback to home health agencies, prior to the public reporting of this measure, based on Medicare FFS claims data from discharges in CYs 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CYs 2016 and 2017. We plan to submit this proposed measure to the NQF for consideration for endorsement.

We invite public comment on our proposal to adopt the measure, Discharge to Community—PAC HH QRP for the HH QRP.

3. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Post-Acute Care Home Health Quality Reporting Program

Section 1899B(d)(1)(C) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is October 1, 2016 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates. We are proposing the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP as a Medicare FFS claims-based measure to meet this requirement beginning with the CY 2018 payment determination.

The proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries that take place within 30 days of a HH discharge. The HH admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay, which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute-care hospital or a LTCH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for HHAs. Because the measure denominator is based on HH admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after HH discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.[74][75] The MedPAC estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered "potentially preventable."[76] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12 billion for 30-day, $8 billion for 15-day, and $5 billion for 7-day readmissions.[77] For hospital readmissions from one post-acute care setting, SNFs, MedPAC deemed 76 percent of these readmissions as "potentially avoidable"—associated with $12 billion in Medicare expenditures.[78] Mor *et al.* analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3 billion in expenditures.[79] An analysis of data from a nationally representative sample of Medicare FFS beneficiaries receiving home health services in 2004 show that home health patients receive significant amounts of acute and post-acute services after discharge from home health care. Within 30 days of discharge from home health, 29 percent of patients were admitted to a hospital.[80] Focusing on readmissions, Madigan and colleagues studied 74,580 Medicare home health patients with a rehospitalization within 30 days of the index hospital discharge. The 30-day rehospitalization rate was 26 percent with the largest proportion related to a cardiac-related diagnosis (42 percent).[81] Fewer studies have investigated potentially preventable readmission rates from other post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting as well as in PAC. For example, we developed the following measure: Rehospitalization During the First 30 Days of Home Health (NQF #2380), as well as similar measures for other PAC providers (NQF #2502 for IRFs, NQF #2510 for SNFs NQF #2512 for LTCHs).[82] These measures are endorsed by the NQF, and the NQF-endorsed measure (NQF #2380) was adopted into the HH QRP in the CY 2014 HH PPS final rule (80 FR 68691 through 68692). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[83][84][85] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.[86][87] Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.[88][89][90]

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

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[81] Madigan, E. A., N. H. Gordon, et al. "Rehospitalization in a national population of home health care patients with heart failure." Health Serv Res 47(6): 2013; 2316–2338.

[82] National Quality Forum: All-Cause Admissions and Readmissions Measures. pp. 1–319, April 2015. Available from *http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx.*

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[86] Kramer, A., Lin, M., Fish, R., et al. Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement. pp. 1–42, 2015. Available from *http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0.*

[87] Kramer, A., Lin, M., Fish, R., et al. Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures. pp. 1–75, 2014. Available from *http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0.*

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[90] Walsh, E.G., Wiener, J.M., Haber, S., et al. Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. J. Am. Geriatr. Soc. 60(5):821–829, 2012. doi:10.1111/j.1532-5415.2012.03920.

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events

Additional details regarding the definition for potentially preventable readmissions are available in the document titled Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

This proposed measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the Rehospitalization During the First 30 Days of Home Health measure (NQF #2380), this proposed measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* In addition to the CMS Planned Readmission Algorithm, this proposed measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

The proposed measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates an agency-specific effect, common to patients treated in each agency. This proposed measure is calculated for each HHA based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an HH discharge, including the estimated agency effect, to the estimated predicted number of risk-adjusted, unplanned hospital readmissions for the same patients treated at the average HHA. A ratio above 1.0 indicates a higher than expected readmission rate (worse), while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all HH episodes. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible HH episode is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate.

This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for HHAs accounts for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, comorbidities, length of stay during the patient's prior proximal hospital stay, intensive care and coronary care unit (ICU and CCU) utilization, ESRD status, and number of acute care hospitalizations in the preceding 365 days.

The proposed measure is calculated using 3 consecutive calendar years of FFS data, in order to ensure the statistical reliability of this measure for smaller agencies. In addition, we are proposing a minimum of 20 eligible episodes for public reporting of the proposed measure. For technical information about this proposed measure including information about the measure calculation, risk adjustment, and exclusions, we refer readers to our Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The NQF-convened MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

At the time of the MAP, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the Rehospitalization During the First 30 Days of Home Health Measure (NQF #2380) adopted into the HH QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the HH QRP for the CY 2018 payment determination and subsequent years given the evidence previously discussed above.

We plan to submit the proposed measure to the NQF for consideration of endorsement. If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this proposed measure, based on 3 calendar years of claims data from discharges in CYs 2014, 2015 and 2016. We intend to publicly report this proposed measure using claims data from CYs 2015, 2016 and 2017.

We are inviting public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP.

4. Proposal To Address the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post-Acute Care Home Health Quality Reporting Program

Section 1899B(c)(1)(C) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(i) is October 1, 2018 for SNFs, IRFs and LTCHs and January 1, 2017 for HHAs), the Secretary specify quality measures to address the domain of medication reconciliation. We are proposing to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP for the HH QRP as a patient-assessment based, cross-setting quality measure to meet this requirement with data collection beginning January 1, 2017, beginning with the CY 2018 payment determination.

This proposed measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the proposed quality measure reports the percentage of patient episodes in which a drug regimen review was conducted at the start of care or resumption of care and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that episode. For this proposed quality measure, a drug regimen review is defined as the review of all medications or drugs the patient is taking in order to identify potential clinically significant medication issues. This proposed quality measure utilizes both the processes of medication reconciliation and a drug regimen review in the event an actual or potential medication issue occurred. The proposed measure informs whether the PAC agency identified and addressed each clinically significant medication issue and if the agency responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.[91] This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs). Medication discrepancies occur when there is conflicting information documented in the medical records.

The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs.[92] The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.[93] The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.[94] There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.[95] [96] [97] [98]

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs,[99] [100] including subsequent emergency room visits and re-hospitalizations. ADEs are associated with an estimated $3.5 billion in annual health care costs and 7,000 deaths annually.[101]

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE.[102] [103] [104] [105] [106] [107]

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Continued

Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly $7.2 billion annually.[108] [109]

There is strong evidence that medication discrepancies can occur during transfers from acute care facilities to post-acute care facilities. Discrepancies can occur when there is conflicting information documented in the medical records. Almost one-third of medication discrepancies have the potential to cause patient harm.[110] Potential medication problems upon admission to HHAs have been reported as occurring at a rate of 39 percent of reviewed charts[111] and mean medication discrepancies between 2.0 ±2.3 and 2.1 ±2.4.[112] Similarly, medication discrepancies were noted as patients transitioned from the hospital to home health settings.[113] An estimated fifty percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[114]

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving post-acute care setting when performing medication reconciliation.[115] [116] Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.[117] [118] [119] [120] [121] [122] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[123] [124] With respect to older patients who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,[125] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[126] The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC settings each year. For example, in 2013, 3.2 million Medicare FFS beneficiaries had a home health episode.

A TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Video Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this proposed measure. The public comment summary report for the proposed measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP. The MAP encouraged continued development of the proposed quality measure for the HH QRP to meet the mandate of the IMPACT Act. The MAP agreed with the measure gaps identified by CMS including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAPs recommendations for this measure is available at *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.*

Since the MAP's review, we have continued to refine this proposed

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measure in compliance with the MAP's recommendations. The proposed measure is both consistent with the information submitted to the MAP and supports its scientific acceptability for use in the HH QRP. Therefore, we are proposing this measure for implementation in the HH QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HH settings of care: Care for Older Adults (COA) (NQF #0553). The quality measure, Care for Older Adults (COA) (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA) (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, which reports the percentage of patient episodes in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician or physician-designee occurred each time one or more potential clinically significant medication issues were identified throughout that episode.

After careful review of both quality measures, we have decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings;
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, requires the identification of clinically potential medication issues at the beginning, during and at the end of the patient's episode to capture data on each patient's complete HH episode; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population;
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid time frame (by midnight of the next calendar day); whereas, the Care for Older Adults (COA) (NQF #0553) quality measure does not include any follow-up or time frame in which the follow-up would need to occur;
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, does not have age exclusions; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure limits the measure's population to patients aged 66 and older; and
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, would be reported to HHAs quarterly to facilitate internal quality monitoring and quality improvement in areas such as patient safety, care coordination and patient satisfaction; whereas, the Care for Older Adults (COA) (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP, for the HH QRP for CY 2018 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration of endorsement.

The calculation of the proposed quality measure would be based on the data collection of three standardized items that would be added to the OASIS. The collection of data by means of the standardized items would be obtained at start or resumption of care and end of care. For more information about the data submission required for this proposed measure, we refer readers to Section I. Form, Manner, and Timing of OASIS Data Submission and OASIS Data for Annual Payment Update.

The standardized items used to calculate this proposed quality measure will replace existing items currently used for data collection within the OASIS. The proposed measure denominator is the number of patient episodes with an end of care assessment during the reporting period. The proposed measure numerator is the number of episodes in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Start or resumption of care; and (2) end of care with a look back through the home health patient episode with all potential clinically significant medication issues identified during the course of care and followed-up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this proposed measure, including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, we refer readers to the document titled Proposed Measure Specifications for Measures Proposed in the CY 2017 HH QRP proposed rule available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP, would be collected using the OASIS with submission through the QIES ASAP system.

We invite public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP for CY 2018 APU determination and subsequent years.

H. HH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We invite public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 33 for use in future years in the HH QRP.

TABLE 33: HH QRP Quality Measures under Consideration for Future Years

IMPACT Act Domain	Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions
IMPACT Act Measure	• Transfer of health information and care preferences when an individual transitions
IMPACT Act Domain	Incidence of major falls
IMPACT Act Measure	• Application of NQF #0674 - Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)
IMPACT Act Domain	Functional status, cognitive function, and changes in function and cognitive function
IMPACT Act Measure	• Application of NQF #2631 - Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function
NQS Priority	Patient- and Caregiver-Centered Care
Measures	• Application of NQF #2633 - Change in Self-Care Score for Medical Rehabilitation Patients • Application of NQF #2634 - Change in Mobility Score for Medical Rehabilitation Patients • Application of NQF #2635 - Discharge Self-Care Score for Medical Rehabilitation Patients • Application of NQF #2636 - Discharge Mobility Score for Medical Rehabilitation Patients • Application of NQF #0680 - Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)

We are developing a measure related to the IMPACT Act domain, "Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions." We are also considering application of two IMPACT Act measures to the HH QRP, to assess the incidence of falls with major injury and functional assessment and goals setting. We are additionally considering application of four standardized functional measures to the HH QRP; two that would assess change in function across the HH episode and two that would assess actual function at discharge relative to expected function. Finally, we are considering a measure related to health and well-being, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).

Based on input from stakeholders, we have identified additional concept areas for potential future measure development for the HH QRP. These include "efficacy" measures that pair processes, such as assessment and care planning, with outcomes, such as emergency treatment for injuries or increase in pain. The prevalence of mental health and behavioral problems was identified as an option to address outcomes for special populations. In addition, CMS is considering development of measures that assess if functional abilities were maintained during a care episode and composite measures that combine multiple evidence-based processes. CMS invites feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

I. Form Manner and Timing of OASIS Data Submission and OASIS Data for Annual Payment Update

1. Regulatory Authority

The HH conditions of participation (CoPs) at § 484.55(d) require that the comprehensive assessment be updated and revised (including the administration of the OASIS) no less frequently than: (1) The last 5 days of every 60 days beginning with the start of care date, unless there is a beneficiary-elected transfer, significant change in condition, or discharge and return to the same HHA during the 60-day episode; (2) within 48 hours of the patient's return to the home from a hospital admission of 24-hours or more for any reason other than diagnostic tests; and (3) at discharge.

It is important to note that to calculate quality measures from OASIS data, there must be a complete quality episode, which requires both a Start of Care (initial assessment) or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS assessment. Failure to submit sufficient OASIS assessments to allow calculation of quality measures, including transfer and discharge assessments, is a failure to comply with the CoPs.

HHAs are not required to submit OASIS data for patients who are excluded from the OASIS submission requirements as described in the December 23, 2005, final rule "Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies" (70 FR 76202).

As set forth in the CY 2008 HH PPS final rule (72 FR 49863), HHAs that become Medicare certified on or after May 31 of the preceding year are not subject to the OASIS quality reporting requirement nor any payment penalty for quality reporting purposes for the following year. For example, HHAs certified on or after May 31, 2014, are not subject to the 2 percentage point reduction to their market basket update for CY 2015. These exclusions only affect quality reporting requirements and payment reductions, and do not affect the HHA's reporting responsibilities as announced in the December 23, 2005 OASIS final rules (70 FR 76202).

2. Home Health Quality Reporting Program Requirements for CY 2017 Payment and Subsequent Years

In the CY 2014 HH PPS final rule (78 FR 72297), we finalized a proposal to consider OASIS assessments submitted by HHAs to CMS in compliance with HH CoPs and Conditions for Payment for episodes beginning on or after July 1, 2012, and before July 1, 2013, as fulfilling one portion of the quality reporting requirement for CY 2014.

In addition, we finalized a proposal to continue this pattern for each subsequent year beyond CY 2014. OASIS assessments submitted for episodes beginning on July 1 of the calendar year 2 years prior to the calendar year of the Annual Payment Update (APU) effective date and ending June 30 of the calendar year one year prior to the calendar year of the APU effective date; fulfill the OASIS portion of the HH QRP requirement.

3. Previously Established Pay-for-Reporting Performance Requirement for Submission of OASIS Quality Data

Section 1895(b)(3)(B)(v)(I) of the Act states that for 2007 and each subsequent year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points if a home health agency does not submit quality data to the Secretary in accordance with subclause (II) for such a year. This pay-for-reporting requirement was implemented on January 1, 2007. In the CY 2016 HH PPS final rule (80 FR 68703 through 68705), we finalized a proposal to define the quantity of OASIS assessments each HHA must submit to meet the pay-for-reporting requirement. We designed a pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data. The performance system is based on the principle that each HHA is expected to submit a minimum set of two matching assessments for each patient admitted to their agency. These matching assessments together create what is considered a quality episode of care, consisting ideally of a Start of Care (SOC) or Resumption of Care (ROC) assessment and a matching End of Care (EOC) assessment.

Section 80 of Chapter 10 of the Medicare Claims Processing Manual states, "If a Medicare beneficiary is covered under an MA Organization during a period of home care, and subsequently decides to change to Medicare FFS coverage, a new start of care OASIS assessment must be completed that reflects the date of the beneficiary's change to this pay source." We wish to clarify that the SOC OASIS assessment submitted when this change in coverage occurs will not be used in our determination of a quality assessment for the purpose of determining compliance with data submission requirements. In such a circumstance, the original SOC or ROC assessment submitted while the Medicare beneficiary is covered under an MA Organization would be considered a quality assessment within the pay-for-reporting, APU, Quality Assessments Only methodology. For further information on successful submission of OASIS assessments, types of assessments submitted by an HHA that fit the definition of a quality assessment, defining the "Quality Assessments Only" (QAO) formula, and implementing a pay-for-reporting performance requirement over a 3-year period, please see the CY 2016 HH PPS final rule (80 FR 68704 to 68705). HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance requirement for CY 2017 (reporting period July 1, 2015 to June 30, 2016), 80 percent for CY 2018 (reporting period July 1, 2016 to June 30, 2017) and 90 percent for CY 2019 (reporting period July 1, 2017 to June 30, 2018) or be subject to a 2 percentage point reduction to their market basket update for that reporting period.

In this proposed rule we are not proposing any additional policies related to the pay-for-reporting performance requirement.

4. Proposed Timeline and Data Submission Mechanisms for Measures Proposed for the CY 2018 Payment Determination and Subsequent Years

a. Claims Based Measures

The MSPB–PAC HH QRP, Discharge to Community—PAC HH QRP, and Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, which we have proposed in this proposed rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection will be required from HHAs. As previously discussed in V.G., for the Discharge to Community—PAC HH QRP measure we propose to use 2 years of claims data, beginning with CYs 2015 and 2016 claims data to inform confidential feedback and CYs 2016 and 2017 claims data for public reporting. For the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP we propose to use 3 years of claims data, beginning with CY 2014, 2015 and 2016 claims data to inform confidential feedback reports for HHAs, and CY 2015, 2016 and 2017 claims data for public reporting. For the MSPB–PAC HH QRP measure, we propose to use one year of claims data beginning with CY 2016 claims data to inform confidential feedback reports for HHAs, and CY 2017 claims data for public reporting for the HH QRP.

b. Assessment-Based Measures Using OASIS Data Collection

As discussed in section V.G of this proposed rule, for the proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP, affecting CY 2018 payment determination and subsequent years, we are proposing that HHAs would submit data by completing data elements on the OASIS and then submitting the OASIS to CMS through the QIES ASAP system beginning January 1, 2017. For more information on HH QRP reporting through the QIES ASAP system, refer to CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIOASISUserManual.html.*

We propose to use standardized data elements in OASIS C2 to calculate the proposed measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP. The data elements necessary to calculate this measure using the OASIS are available on our Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

We invite public comments on the proposed HH QRP data collection requirements for the proposed measure affecting CY 2018 payment determination and subsequent years.

5. Proposed Timeline and Data Submission Mechanisms for the CY 2018 Payment Determination and Subsequent Years for New HH QRP Assessment-Based Quality Measure

In the CY 2016 HH PPS final rule (80 FR 68695 through 68698) for the FY 2018 payment determination, we finalized that HHAs must submit data on the quality measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) using CY 2017 data, for example, patients who are admitted to the HHA on and after January 1, 2017, and discharged from the HHA up to and including December 31, 2017. However, for CY 2018 APU purposes this timeframe would be impossible to achieve, given the processes we have established associated with APU determinations, such as the opportunity for providers to seek reconsideration for determinations of non-compliance. Therefore, for both the measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP, we propose that we would collect two quarters of data for CY 2018 APU determination to remain consistent with the January release schedule for the OASIS and to give HHAs sufficient time to update their systems so that they can comply with the new data reporting requirements, and to give us a sufficient amount of time to determine compliance for the CY 2018 program. The proposed use of two quarters of data for the initial year of quality reporting is consistent with the approach we have used to implement new measures in a number of other QRPs, including the LTCH, IRF, and Hospice QRPs in which only one quarter of data was used.

We invite public comments on our proposal to adopt a calendar year data collection time frame, using an initial 6-month reporting period from January 1, 2017, to June 30, 2017 for CY 2018 payment determinations, for the application of measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP.

6. Data Collection Timelines and Requirements for the CY 2019 Payment Determinations and Subsequent Years

In CY 2014 HH PPS final rule (78 FR 72297), we finalized our use of a July 1–June 30 time frame for APU determinations. In alignment with the previously established timeframe data collection for a given calendar year APU determination time period, beginning with the CY 2019 payment determination, we propose for both the finalized measure, NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay), and the proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP, to use 12 months of data collection, specifically assessments submitted July 1, 2017 through June 30, 2018, for the CY 2019 payment determination. We further propose to continue to use the same 12-month timeframe of July 1–June 30 for these measures for subsequent years for APU determinations.

We invite comment on these proposals for the data collection timelines and requirements.

7. Proposed Data Review and Correction Timeframes for Data Submitted Using the OASIS Instrument

In addition, to remain consistent with the SNF, LTCH and IRF QRPs, as well as to comply with the requirements of section of section 1899B(g) of the Act, we are also proposing to implement calendar year provider review and correction periods for the OASIS assessment-based quality measures implemented into the HH QRP in satisfaction of the IMPACT Act, that is, finalized NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) and the proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP. More specifically, we are proposing that HHAs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER generated Quality Measure reports) to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, HHAs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, once the quarterly submission deadline occurs, the data is "frozen" and calculated for public reporting and providers can no longer submit any corrections. As laid out in Table 34, the first calendar year reporting quarter is January 1, 2017 through March 31, 2017. The final deadline for submitting corrected data would be August 15, 2017 for CY Quarter 1, and subsequently and sequentially, November 15, 2017 for CY 2017 Quarter 2, February 15, 2018 for CY 2017 Quarter 3 and May 15, 2018 for CY 2017 Quarter 4. We note that this proposal to review and correct data does not replace other requirements associated with timely data submission. We would encourage HHAs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

TABLE 34: Proposed CY Data Collection/Submission Quarterly Reporting Periods and Data Submission Deadlines* Affecting Finalized and Proposed Assessment-based Measures

Quality Measures	Data Collection Source	Proposed Data Collection/ Ssubmission Quarterly Reporting Period*	Proposed Quarterly Review and Correction Periods and Data Submission Quarterly Deadlines *
NQF # 0678:Application of Percent of Patients or Residents with Pressure Ulcers that are New or Worsened Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP	OASIS	CY 17 Q1 1/1/2017-3/31/2017	CY 2017 Q1 Deadline: **August 15, 2017**
		CY 17 Q2 4/1/2017-6/30/17	CY 2017 Q2 Deadline: **November 15, 2017**
		CY 17 Q3 7/1/2017-9/30/2017	CY 2017 Q3 Deadline: **February 15, 2018**
		CY 17 Q4 10/1/2017-12/31/2017	CY 2017 Q4 Deadline May 15, 2018

*We note that the submission deadlines provided pertain to the correction of data and that the submission of OASIS data must continue to adhere to all submission deadline requirements as imposed under the Conditions of Participation.

We invite public comments on our proposal to adopt a calendar year data collection time frame, with a 4.5 month period of time for review and correction beginning with CY 2017 for the measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) that we finalized in the CY 2016 HH PPS rule, and the CY 2017 HH PPS proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC HH QRP for the HH QRP.

Further, we propose that the OASIS assessment-based measures already finalized for adoption into the HH QRP follow a similar CY schedule of data reporting using quarterly data collection/submission reporting periods followed by 4.5 months during which providers will have an opportunity to review and correct their data up until the quarterly data submission deadlines as provided in Table 35 for all reporting years unless otherwise specified. This policy would apply to all proposed and finalized assessment-based measures in the HH QRP.

TABLE 35—PROPOSED CY DATA COLLECTION SUBMISSION QUARTERLY REPORTING PERIODS, QUARTERLY REVIEW AND CORRECTION PERIODS AND DATA SUBMISSION DEADLINES FOR MEASURES SPECIFIED IN SATISFACTION OF THE IMPACT ACT IN SUBSEQUENT YEARS

Proposed CY data collection quarter	Proposed data collection/submission quarterly reporting period	Proposed quarterly review and correction periods and data submission quarterly deadlines *	Proposed correction deadlines *
Quarter 1	January 1–March 31	April 1–August 15	August 15.
Quarter 2	April 1–June 30	July 1–November 15	November 15.
Quarter 3	July 1–September 30	October 1–February 15	February 15.
Quarter 4	October 1–December 31	January 1–May 15	May 15.

*We note that the submission deadlines provided pertain to the correction of data and that the submission of OASIS data must continue to adhere to all submission deadline requirements as imposed under the Conditions of Participation.

We invite public comment on our use of CY quarterly data collection/submission reporting periods with quarterly data submission deadlines that follow a period of approximately 4.5 months of time to enable the review and correction of such data for OASIS assessment-based measures.

J. Public Display of Quality Measure Data for the HH QRP and Procedures for the Opportunity To Review and Correct Data and Information

Medicare home health regulations, as codified at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. Section 1899B(g) of the Act requires that data and information of provider performance on quality measures and resource use and other measures be made publicly available beginning not later than 2 years after the applicable specified application date. In future rulemaking, we intend to propose a policy to publicly display performance information for individual HHAs on IMPACT Act measures, as required under the Act. In addition, sections 1895(b)(3)(B)(v)(III) and 1899B(g) of the Act require the Secretary to establish procedures for making data submitted under subclause (II) available to the public. Under section 1899B(g)(2), such procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital IQR Program, that a home health agency has the opportunity to review and submit corrections to its data and information that are to be made public for the agency prior to such data being made public through a process consistent with the Hospital Inpatient Quality Reporting Program (Hospital IQR). We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to ensuring that the data made available to the public are meaningful. Further, we agree that measures for comparing performance across home health agencies requires should be constructed from data collected in a standardized and uniform manner. In this proposed rule, we are proposing procedures that would allow individual HHAs to review and correct their data and information on IMPACT Act measures that are to be made public before those measure data are made public.

1. Proposals for the Review and Correction of Data Used To Calculate the Assessment-Based Measures Prior to Public Display

As provided in section V.I.7., and in Table 34, for assessment-based measures, we are proposing to provide confidential feedback reports to HHAs that contain performance information that the HHAs can review, during the review and correction period, and correct the data used to calculate the measures for the HH QRP that the HHA submitted via the QIES ASAP system. In addition, during the review period, the HHA would be able to request correction of any errors in the assessment-based measure rate calculations.

We propose that these confidential feedback reports would be available to each HHA using the Certification and Survey Provider Enhanced Reporting (CASPER) System. We refer to these reports as the HH Quality Measure (QM) Reports. We intend to provide monthly updates to the data contained in these reports that pertain to assessment-based data, as data become available. The reports will contain both agency- and patient-level data used to calculate the assessment-based quality measures. The CASPER facility level QM reporting would include the numerator, denominator, agency rate, and national rate. The CASPER patient-level QM Reports would also contain individual patient information that HHAs can use to identify patients that were included in the quality measures so as to identify any potential errors. In addition, we would make other reports available to HHAs through the CASPER System, including OASIS data submission reports and provider validation reports, which would contain information on each HHA's data submission status, including details on all items the HHA submitted in relation to individual assessments and the status of the HHA's assessment (OASIS) records that they submitted. When available, additional information regarding the content and availability of these confidential feedback reports would be provided on the HH QRP Web site *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/index.html.*

As previously proposed in section V.I.7., for those measures that use assessment-based data, HHAs would have 4.5 months after the conclusion of each reporting quarter to review and update their reported measure data for the quarter, including correcting any errors that they find on the CASPER-generated Review and Correct, QM reports pertaining to their assessment-based data used to calculate the assessment-based measures. However, at the conclusion of this 4.5 month review and correction period, the data reported for that quarter would be "frozen" and used to calculate measure rates for public reporting. We would encourage HHAs to submit timely assessment data during each quarterly reporting period and to review their data and information early during the 4.5 month review and correction period so they can identify errors and resubmit data before the data submission deadline.

We believe that the proposed data submission period along with a review and correction period, consisting of the reporting quarter plus approximately 4.5 months, is sufficient time for HHAs to submit, review and, where necessary, correct their data and information. We also propose that, in addition to the data submission/correction and review period, HHAs will have a 30-day preview period prior to public display during which they can preview the performance information on their measures that will be made public. We also propose to provide this preview report using the Certification and Survey Provider Enhanced Reporting (CASPER) System because HHAs are familiar with this system. The CASPER preview reports for the reporting quarter would be available after the 4.5 month review and correction period ends, and would be refreshed quarterly or annually for each measure, depending on the length of the reporting period for that measure. We propose to give HHAs 30 days to review this information, beginning from the date on which they can access the preview report. Corrections to the underlying data would not be permitted during this time; however, HHAs would be able to ask for a correction to their measure calculations during the 30-day preview period. If we determine that the measure, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure and publish the corrected rate at the time of the next scheduled public display date. This process is consistent with informal processes used in the Hospital IQR program. If finalized, we intend to utilize a subregulatory mechanism, such as our HH QRP Web site, to explain the technical details for how and when providers may contest their measure calculations. We further propose to increase the current preview period of 15 days to 30 days beginning with the public display of the measures finalized for the CY 2018 payment determination. This preview period would include all measures that are to be publicly displayed under the current quarterly refresh schedule used for posting quality measure data on the Medicare.gov Home Health Compare site.

We invite public comment on these proposals.

2. Proposals for Review and Correction of Data Used To Calculate Claims-Based Measures Prior To Public Display

In addition to assessment-based measures, we have also proposed claims-based measures for the HH QRP. As noted previously, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR program. Under the Hospital IQR Program's procedures, for claims-based measures, we give hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We propose to adopt a similar process for the HH QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC and Hospital VBP programs, we propose to make available through the CASPER system a confidential preview report that will contain information pertaining to their claims-based measure rate calculations, including agency and national rates. This information would be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the rates.

We propose to create data extracts using claims data for these claims based measures, at least 90 days after the last discharge date in the applicable period (12 calendar months preceding), which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017, for data collection January 1, 2017, through December 31, 2017, we would create the data extract on approximately March 31, 2018, at the earliest, and use that data to calculate the claims-based measures for the 2017 reporting period. We propose that beginning with data for measures that will be publicly displayed by January 1, 2019, and for which will need to coincide with the quarterly refresh schedule on Home Health Compare, the claims-based measures will be calculated at least 90 days after the last discharge date using claims data from the applicable reporting period. This timeframe allows us to balance the need to provide timely program information to HHAs with the need to calculate the claims-based measures using as complete a data set as possible. Since HHAs would not be able to submit corrections to the underlying claims snapshot or add claims (for those measures that use HH claims) to this data set, at the conclusion of the 90-day period following the last date of discharge used in the applicable period, we would consider the HH claims data to be complete for purposes of calculating the claims-based measures. We wish to convey the importance that HHAs ensure the completeness and correctness of their claims prior to the claims "snapshot". We seek to have as complete a data set as possible. We recognize that the proposed approximately 90 day "run-out" period is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed approximately 90 day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted, and/or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to HHAs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay, both for HHAs and for us to deliver timely calculations to HHAs for quality improvement.

As noted, under this proposed procedure, during the 30-day preview period, HHAs would not be able to submit corrections to the underlying claims data or add new claims to the data extract. This is for two reasons. First, for certain measures, some of the claims data used to calculate the measure are derived not from the HHA's claims, but from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP uses claims data submitted by the hospital to which the patient was readmitted. HHAs are not able to make corrections to these hospital claims, although the agency could request that the hospital reconfirm that its submissions are correct. Second, even where HHA claims are used to calculate the measures, it would not be not possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static "snapshot" of the claims in order to perform the necessary measure calculations.

As noted previously, we propose to provide HHAs a 30-day preview period to review their confidential preview reports. HHAs would have 30 days from the date the preview report is made available to review this information. The 30-day preview period would be the only time when HHAs would be able to see their claims-based measure rates before they are publicly displayed. HHAs could request that we correct our measure calculation during the 30-day preview period if the HHA believes the measure rate is incorrect. If we agree that the measure rate, as it is displayed in the preview report, contains a calculation error, we would suppress the data on the public reporting Web site, recalculate the measure, and publish the corrected measure rate at the time of the next scheduled public display date. If finalized, we intend to utilize a subregulatory mechanism, such as our HH QRP Web site, to explain the technical details regarding how and when providers may contest their measure calculations. We refer readers to the discussion inV.I.2 for additional information on these preview reports.

In addition, because the claims-based measures used for the HH QRP are re-calculated on an annual basis, these confidential CASPER QM preview reports for claims-based measures would be refreshed annually. An annual refresh is being utilized to ensure consistency in our display of claims based measures, and it will include both claims-based measures that satisfy the IMPACT Act, as well as all other HH QRP claims-based measures.

We invite public comment on these proposals for the public display of quality measure data.

K. Mechanism for Providing Feedback Reports to HHAs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback measure reports to post-acute care providers on their performance on the measures specified under paragraphs (c)(1) and (d)(1), beginning 1 year after the specified application date that applies to such measures and PAC providers. We propose to build upon the current confidential quality measure reports we already generate for HHAs so as to also provide data and information on the measures implemented in satisfaction of the IMPACT Act. As a result, HHAs could review their performance on these measures, as well as those already adopted in the HH QRP. We propose that these additional confidential feedback reports would be made available to each HHA through the CASPER System. Data contained within these CASPER reports would be updated, as previously described, on a monthly basis as the data become available except for claims-based measures, which will only be updated on an annual basis.

We intend to provide detailed procedures to HHAs on how to obtain their new confidential feedback reports in CASPER on the HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html.* We also propose to use the QIES ASAP system to provide these new confidential quality measure reports in a manner consistent with how HHAs have obtained such reports to date. The QIES ASAP system is a confidential and secure system with access granted to providers, or their designees.

We invite public comment on this proposal to satisfy the requirement to provide confidential feedback reports to

HHAs specific to the requirements of the Act.

L. Home Health Care CAHPS® Survey (HHCAHPS)

In the CY 2016 HH PPS final rule (80 FR 68623), we stated that the home health quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAHPS) Survey for the CY 2017 and 2018 Annual Payment Update (APU) periods. We are continuing to maintain the stated HHCAHPS data requirements for CY 2017 and CY 2018 that were stated in CY 2016 and in previous HH PPS rules, for the continuous monthly data collection and quarterly data submission of HHCAHPS data.

1. Background and Description of HHCAHPS

As part of the HHS Transparency Initiative, we implemented a process to measure and publicly report patient experiences with home health care, using a survey developed by the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program and endorsed by the National Quality Forum (NQF) in March 2009 (NQF Number 0517) and NQF re-endorsed in 2015. The HHCAHPS Survey is approved under OMB Control Number 0938–1066. The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The Home Health Care CAHPS® (HHCAHPS) survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care.

Prior to this survey, there was no national standard for collecting information about patient experiences that enabled valid comparisons across all HHAs. The history and development process for HHCAHPS has been described in previous rules and is also available on the official HHCAHPS Web site at *https://homehealthcahps.org* and in the annually-updated *HHCAHPS Protocols and Guidelines Manual,* which is downloadable from *https://homehealthcahps.org.*

Since April 2012, for public reporting purposes, we report five measures from the HHCAHPS Survey—three composite measures and two global ratings of care that are derived from the questions on the HHCAHPS survey. The publicly reported data are adjusted for differences in patient mix across HHAs. We update the HHCAHPS data on Home Health Compare on *www.medicare.gov* quarterly. Each HHCAHPS composite measure consists of four or more individual survey items regarding one of the following related topics:

- Patient care (Q9, Q16, Q19, and Q24);
- Communications between providers and patients (Q2, Q15, Q17, Q18, Q22, and Q23); and
- Specific care issues on medications, home safety, and pain (Q3, Q4, Q5, Q10, Q12, Q13, and Q14).

The two global ratings are the overall rating of care given by the HHA's care providers (Q20), and the patient's willingness to recommend the HHA to family and friends (Q25).

The HHCAHPS survey is currently available in English, Spanish, Chinese, Russian, and Vietnamese. The OMB number on these surveys is the same (0938–1066). All of these surveys are on the Home Health Care CAHPS® Web site, *https://homehealthcahps.org.* We continue to consider additional language translations of the HHCAHPS in response to the needs of the home health patient population.

All of the requirements about home health patient eligibility for the HHCAHPS survey and conversely, which home health patients are ineligible for the HHCAHPS survey are delineated and detailed in the *HHCAHPS Protocols and Guidelines Manual,* which is downloadable at *https://homehealthcahps.org.* Home health patients are eligible for HHCAHPS if they received at least two skilled home health visits in the past 2 months, which are paid for by Medicare or Medicaid.

Home health patients are ineligible for inclusion in HHCAHPS surveys if one of these conditions pertains to them:

- Are under the age of 18;
- Are deceased prior to the date the sample is pulled;
- Receive hospice care;
- Receive routine maternity care only;
- Are not considered survey eligible because the state in which the patient lives restricts release of patient information for a specific condition or illness that the patient has; or
- Are "No Publicity" patients, defined as patients who on their own initiative at their first encounter with the HHAs make it very clear that no one outside of the agencies can be advised of their patient status, and no one outside of the HHAs can contact them for any reason.

We stated in previous rules that Medicare-certified HHAs are required to contract with an approved HHCAHPS survey vendor. This requirement continues, and Medicare-certified agencies also must provide on a monthly basis a list of their patients served to their respective HHCAHPS survey vendors. Agencies are not allowed to influence at all how their patients respond to the HHCAHPS survey.

As previously required, HHCAHPS survey vendors are required to attend introductory and all update trainings conducted by CMS and the HHCAHPS Survey Coordination Team, as well as to pass a post-training certification test. We have approximately 30 approved HHCAHPS survey vendors. The list of approved HHCAHPS survey vendors is available at *https://homehealthcahps.org.*

2. HHCAHPS Oversight Activities

We stated in prior final rules that all approved HHCAHPS survey vendors are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that approved HHCAHPS survey vendors follow the *HHCAHPS Protocols and Guidelines Manual.*

In the CY 2013 HH PPS final rule (77 FR 67094, 67164), we codified the current guideline that all approved HHCAHPS survey vendors fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

3. HHCAHPS Requirements for the CY 2017 APU

For the CY 2017 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2017, APU includes the second quarter 2015 through the first quarter 2016 (the months of April 2015 through March 2016). HHAs are required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2015 by 11:59 p.m., EST on October 15, 2015; for the third quarter 2015 by 11:59 p.m., EST on January 21, 2016; for the fourth quarter 2015 by 11:59 p.m., EST on April 21, 2016; and for the first quarter 2016 by 11:59 p.m., EST on July 21, 2016. These deadlines are firm; no exceptions are permitted.

For the CY 2017 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2014, through March 31, 2015, are exempt from the HHCAHPS data collection and submission requirements for the CY 2017 APU, upon completion of the CY 2017 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60

HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2014, through March 31, 2015, are required to submit their patient counts on the CY 2017 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2015, to 11:59 p.m., EST to March 31, 2016. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicare-certification on or after April 1, 2015, are exempt from the HHCAHPS reporting requirement for the CY 2017 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2017 APU.

4. HHCAHPS Requirements for the CY 2018 APU

For the CY 2018 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018, APU includes the second quarter 2016 through the first quarter 2017 (the months of April 2016 through March 2017). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2016 by 11:59 p.m., EST on October 20, 2016; for the third quarter 2016 by 11:59 p.m., EST on January 19, 2017; for the fourth quarter 2016 by 11:59 p.m., EST on April 20, 2017; and for the first quarter 2017 by 11:59 p.m., EST on July 20, 2017. These deadlines are firm; no exceptions will be permitted.

For the CY 2018 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2015 through March 31, 2016, are exempt from the HHCAHPS data collection and submission requirements for the CY 2018 APU, upon completion of the CY 2018 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2015, through March 31, 2016, are required to submit their patient counts on the CY 2018 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2016, to 11:59 p.m., EST to March 31, 2017. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicare-certification on or after April 1, 2016, are exempt from the HHCAHPS reporting requirement for the CY 2018 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2018 APU.

5. HHCAHPS Requirements for the CY 2019 APU

For the CY 2019 APU, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018, APU includes the second quarter 2017 through the first quarter 2018 (the months of April 2017 through March 2018). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2017 by 11:59 p.m., EST on October 19, 2017; for the third quarter 2017 by 11:59 p.m., EST on January 18, 2018; for the fourth quarter 2017 by 11:59 p.m., EST on April 19, 2018; and for the first quarter 2018 by 11:59 p.m., EST on July 19, 2018. These deadlines are firm; no exceptions will be permitted.

For the CY 2019 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2016 through March 31, 2017, are exempt from the HHCAHPS data collection and submission requirements for the CY 2019 APU, upon completion of the CY 2019 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2016, through March 31, 2017, are required to submit their patient counts on the CY 2019 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2017, to 11:59 p.m., EST to March 31, 2018. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicare-certification on or after April 1, 2017, are exempt from the HHCAHPS reporting requirement for the CY 2019 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2019 APU.

6. HHCAHPS Requirements for the CY 2020 APU

For the CY 2020 APU, we require continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2020, APU includes the second quarter 2018 through the first quarter 2019 (the months of April 2018 through March 2019). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2018 by 11:59 p.m., EST on October 18, 2018; for the third quarter 2018 by 11:59 p.m., EST on January 17, 2019; for the fourth quarter 2018 by 11:59 p.m., EST on April 18, 2019; and for the first quarter 2019 by 11:59 p.m., EST on July 19, 2019. These deadlines are firm; no exceptions will be permitted.

For the CY 2020 APU, we require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2017, through March 31, 2018, are exempt from the HHCAHPS data collection and submission requirements for the CY 2020 APU, upon completion of the CY 2020 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2017, through March 31, 2018, are required to submit their patient counts on the CY 2020 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2018, to 11:59 p.m., EST to March 31, 2019. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We automatically exempt HHAs receiving Medicare certification after the period in which HHAs do their patient count. HHAs receiving Medicare-certification on or after April 1, 2018 are exempt from the HHCAHPS reporting requirement for the CY 2020 APU. These newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2020 APU.

7. HHCAHPS Reconsiderations and Appeals Process

HHAs should monitor their respective HHCAHPS survey vendors to ensure that vendors submit their HHCAHPS data on time, by accessing their HHCAHPS Data Submission Reports on *https://homehealthcahps.org*. This helps HHAs ensure that their data are submitted in the proper format for data processing to the HHCAHPS Data Center.

We continue the OASIS and HHCAHPS reconsiderations and appeals process that we have finalized and that we have used for prior all periods cited in the previous rules, and utilized in the CY 2012 to CY 2016 APU determinations. We have described the HHCAHPS reconsiderations and appeals process requirements in the APU Notification Letter that we send to the affected HHAs annually in September. HHAs have 30 days from their receipt of the letter informing them that they did not meet the HHCAHPS requirements to reply to us with documentation that supports their requests for reconsideration of the annual payment update to us. It is important that the affected HHAs send in comprehensive information in their reconsideration letter/package because we will not contact the affected HHAs to request additional information or to clarify incomplete or inconclusive information. If clear evidence to support a finding of compliance is not present, then the 2 percent reduction in the annual payment update will be upheld. If clear evidence of compliance is present, then the 2 percent reduction for the APU will be reversed. We notify affected HHAs by December 31 of the decisions that affects payments in the annual year beginning on January 1. If we determine to uphold the 2 percent reduction for the annual payment update, the affected HHA may further appeal the 2 percent reduction via the Provider Reimbursement Review Board (PRRB) appeals process, which is described in the December letter.

8. Summary

We did not propose any changes to the participation requirements, or to the requirements pertaining to the implementation of the Home Health CAHPS® Survey (HHCAHPS). We only updated the information to reflect the dates for future APU years. We again strongly encourage HHAs to keep up-to-date about the HHCAHPS by regularly viewing the official Web site for the HHCAHPS at *https://homehealthcahps.org.* HHAs can also send an email to the HHCAHPS Survey Coordination Team at *hhcahps@rti.org* or to CMS at *homehealthcahps@cms.hhs.gov*, or telephone toll-free (1–866–354–0985) for more information about the HHCAHPS Survey.

VI. Collection of Information Requirements

While this proposed rule contains information collection requirements, this rule does not add new, nor revise any of the existing information collection requirements, or burden estimate. The information collection requirements discussed in this rule for the OASIS–C1 data item set had been previously approved by the Office of Management and Budget (OMB) on February 6, 2014 and scheduled for implementation on October 1, 2014. The extension of OASIS–C1/ICD–9 version was reapproved under OMB control number 0938–0760 with a current expiration date of March 31, 2018. This version of the OASIS will be discontinued once the OASIS–C1/ICD–10 version is approved and implemented. In addition, to facilitate the reporting of OASIS data as it relates to the implementation of ICD–10 on October 1, 2015, CMS submitted a new request for approval to OMB for the OASIS–C1/ICD–10 version under the Paperwork Reduction Act (PRA) process. CMS is requesting a new OMB control number for the proposed revised OASIS item as announced in the 30-day **Federal Register** notice (80 FR 15797). The new information collection request is currently pending OMB approval.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Statement of Need

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of HH services paid under Medicare. In addition, section 1895(b)(3)(A) of the Act requires (1) the computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary, and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to HH services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that was the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase.

Section 421(a) of the MMA requires that HH services furnished in a rural area, for episodes and visits ending on or after April 1, 2010, and before January 1, 2016, receive an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act. Section 210 of the MACRA amended section 421(a) of the MMA to extend the 3 percent increase to the payment amounts for serviced furnished in rural areas for episodes and visits ending before January 1, 2018.

Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. In addition, section 3131(a) of the Affordable Care Act mandates that rebasing must be phased-in over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment (2010) under section 1895(b)(3)(A)(i)(III) of the Act, and be fully implemented in CY 2017.

The HHVBP Model will apply a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and costs of care. The HHVBP Model was implemented in January 2016 as described in the CY 2016 HH PPS final rule.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).The net transfer impacts related to the changes in payments under the HH PPS for CY 2017 are estimated to be −$180 million. The savings impacts related to the HHVBP model are estimated at a total projected 5-year gross savings of $378 million assuming a very conservative savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions. Therefore, we estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule is applicable exclusively to HHAs. Therefore, the Secretary has determined this rule would not have a significant economic impact on the operations of small rural hospitals. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The net transfer impacts related to the changes in payments under the HH PPS for CY 2017 are estimated to be −$180 million. The savings impacts related to the HHVBP Model are estimated at a total projected 6-year gross savings of $378 million assuming a very conservative savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately $146 million. This proposed rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $146 million or more.

1. HH PPS

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2017. Accordingly, the following analysis describes the impact in CY 2017 only. We estimate that the net impact of the policies in this rule is approximately $180 million in decreased payments to HHAs in CY 2017. We applied a wage index budget neutrality factor and a case-mix weights budget neutrality factor to the rates as discussed in section III.C.3 of this proposed rule. Therefore, the estimated impact of the 2017 wage index and the recalibration of the case-mix weights for 2017 is zero. The −$180 million impact reflects the distributional effects of the 2.3 percent HH payment update percentage ($420 million increase), the effects of the fourth year of the four-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit payment rates, and the NRS conversion factor for an impact of −2.3 percent ($420 million decrease), the effects of the −0.97 percent adjustment to the national, standardized 60-day episode payment rate to account for nominal case-mix growth for an impact of −0.9 percent ($160 million decrease), and the effects of the proposed change to the FDL ratio of 0.45 to 0.56 for an impact of −0.1 percent ($20 million decrease). The $180 million in decreased payments is reflected in the last column of the first row in Table 36 as a 1.0 percent decrease in expenditures when comparing CY 2016 payments to estimated CY 2017 payments.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically "significant" only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare-paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule would have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 39, by HHA type and location.

With regards to options for regulatory relief, we note that in the CY 2014 HH PPS final rule we finalized rebasing adjustments to the national, standardized 60-day episode rate, non-routine supplies (NRS) conversion factor, and the national per-visit payment rates for each year, 2014 through 2017 as described in section II.C and III.C.3 of this proposed rule. Since the rebasing adjustments are mandated by section 3131(a) of the Affordable Care Act, we cannot offer HHAs relief from the rebasing adjustments for CY 2017. For the 0.97 percent reduction to the national, standardized 60-day episode payment amount for CY 2017 described in section III.C.3 of this proposed rule, we believe it is appropriate to reduce the national, standardized 60-day episode payment amount to account for the estimated increase in nominal case-mix in order to move towards more accurate payment for the delivery of home health services where payments better align with the costs of providing such services. In the alternatives considered section for the CY 2016 HH PPS proposed rule (80 FR 39839), we note that we considered reducing the 60-day episode rate in CY 2016 only to account for nominal case-mix growth between CY 2012 and CY 2014. However, we instead finalized a reduction to the 60-day episode rate over a three-year period (CY 2016, CY 2017, and CY 2018) to account for estimated nominal case-mix growth between CY 2012 and CY 2014 in order to lessen the impact on HHAs in a given year (80 FR 68646).

Executive Order 13563 specifies, to the extent practicable, agencies should assess the costs of cumulative regulations. However, given potential utilization pattern changes, wage index changes, changes to the market basket forecasts, and unknowns regarding future policy changes, we believe it is neither practicable nor appropriate to forecast the cumulative impact of the rebasing adjustments on Medicare payments to HHAs for future years at this time. Changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes would make it difficult to predict accurately the full scope of the impact upon HHAs for future years beyond CY 2017. We note that the rebasing adjustments to the national, standardized 60-day episode payment rate and the national per-visit rates are capped at the statutory limit of 3.5 percent of the CY 2010 amounts (as described in the preamble in section II.C. of this proposed rule) for each year, 2014 through 2017. The NRS rebasing adjustment will be −2.82 percent in each year, 2014 through 2017.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment will apply in CY 2018 based on PY1 (CY 2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (CY 2020) data. In the CY 2016 HH PPS final rule, the overall impact of HHVBP Model from CY 2018–CY 2022 was approximately a reduction of $380 million. That estimate was based on the five performance years of the Model and only two payment adjustment years. We now estimate that this will be approximately a decrease of $378 million. This estimate represents the five performance years (CY 2016–CY 2020) and applying the payment adjustments from CY 2018 through CY 2021. We assume that the behavior changes and savings will continue into 2021 because HHAs will continue to receive quality reports until July 2021. Although behavior changes and savings could persist into CY 2022, HHAs would not be receiving quality reports so we did not include it in our savings assumptions.

C. Detailed Economic Analysis

1. HH PPS

This rule proposes updates for CY 2017 to the HH PPS rates contained in the CY 2016 HH PPS final rule (80 FR 68624 through 68719). The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2015. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 36 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule. For this analysis, we used an analytic file with linked CY 2015 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2015 (as of March 31, 2016). The first column of Table 36 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2017 wage index. The fourth column shows the payment effects of the CY 2016 case-mix weights. The fifth column shows the effects the 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for nominal case-mix growth. The sixth column shows the effects of the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit payment rates, and NRS conversion factor. For CY 2017, the average impact for all HHAs due to the effects of rebasing is an estimated 2.3 percent decrease in payments. The seventh column shows the effects of revising the FDL ratio used to compute outlier payments from 0.45 to 0.56. The eighth column shows the effects of the change to the outlier methodology. The ninth column shows the effects of the CY 2017 home health payment update percentage.

The last column shows the combined effects of all the policies proposed in this rule. Overall, it is projected that aggregate payments in CY 2017 would decrease by 1.0 percent. As illustrated in Table 36, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2017 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2017 relative to CY 2016, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

TABLE 36— ESTIMATED HOME HEALTH AGENCY IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2017

	Number of Agencies	CY 2017 wage index[1] %	CY 2017 case-mix weights[2] %	60-day episode rate nominal case-mix reduction[3] %	Rebasing[4] %	Revised outlier FDL %	Revised outlier methodology %	HH payment update percentage[5] %	Total %
All Agencies	11,167	0.0	0.0	−0.9	−2.3	−0.1	0.0	2.3	−1.0
Facility Type and Control									
Free-Standing/Other Vol/NP	1,087	−0.2	−0.1	−0.9	−2.2	−0.1	0.9	2.3	−0.3
Free-Standing/Other Proprietary	8,715	0.1	0.0	−0.9	−2.3	−0.1	−0.3	2.3	−1.2
Free-Standing/Other Government	362	0.1	0.1	−0.9	−2.2	−0.1	0.3	2.3	−0.4
Facility-Based Vol/NP	690	−0.1	−0.1	−0.9	−2.2	−0.1	0.8	2.3	−0.3
Facility-Based Proprietary	109	0.0	0.0	−0.9	−2.2	−0.1	0.4	2.3	−0.5
Facility-Based Government	204	−0.3	0.0	−0.9	−2.3	−0.1	0.8	2.3	−0.5
Subtotal: Freestanding	10,164	0.0	0.0	−0.9	−2.3	−0.1	−0.1	2.3	−1.1
Subtotal: Facility-based	1,003	−0.1	0.0	−0.9	−2.2	−0.1	0.8	2.3	−0.2
Subtotal: Vol/NP	1,777	−0.2	−0.1	−0.9	−2.2	−0.1	0.9	2.3	−0.3
Subtotal: Proprietary	8,824	0.1	0.0	−0.9	−2.3	−0.1	−0.3	2.3	−1.2
Subtotal: Government	566	−0.1	0.1	−0.9	−2.3	−0.1	0.5	2.3	−0.5
Facility Type and Control: Rural									
Free-Standing/Other Vol/NP	279	0.1	0.1	−0.9	−2.2	−0.1	0.8	2.3	0.1
Free-Standing/Other Proprietary	873	0.0	−0.1	−0.9	−2.3	−0.1	0.2	2.3	−0.9
Free-Standing/Other Government	261	0.2	0.0	−0.9	−2.4	−0.1	−0.2	2.3	−1.1
Facility-Based Vol/NP	333	0.3	0.1	−0.9	−2.2	−0.1	0.5	2.3	0.0
Facility-Based Proprietary	54	−0.1	0.1	−0.9	−2.3	−0.1	0.5	2.3	−0.5
Facility-Based Government	152	0.1	0.2	−0.9	−2.2	−0.1	0.4	2.3	−0.2
Facility Type and Control: Urban									
Free-Standing/Other Vol/NP	807	−0.3	−0.2	−0.9	−2.2	−0.1	0.9	2.3	−0.5
Free-Standing/Other Proprietary	7,837	0.1	0.0	−0.9	−2.3	−0.1	−0.4	2.3	−1.3
Free-Standing/Other Government	101	0.0	0.0	−0.9	−2.3	−0.1	0.2	2.3	−0.8
Facility-Based Vol/NP	357	−0.2	−0.1	−0.9	−2.2	−0.1	0.9	2.3	−0.3
Facility-Based Proprietary	55	0.1	−0.1	−0.9	−2.2	−0.1	0.3	2.3	−0.6
Facility-Based Government	52	−0.6	−0.1	−0.9	−2.3	−0.1	1.1	2.3	−0.6
Facility Location: Urban or Rural									
Rural	1,952	0.2	0.0	−0.9	−2.3	−0.1	0.0	2.3	−0.8
Urban	9,209	0.0	0.0	−0.9	−2.3	−0.1	0.0	2.3	−1.0
Facility Location: Region of the Country									
Northeast	848	−0.4	0.0	−0.9	−2.1	−0.1	0.8	2.3	−0.4
Midwest	2,992	0.0	0.0	−0.9	−2.4	−0.1	0.4	2.3	−0.7
South	5,310	−0.1	0.0	−0.9	−2.3	−0.1	−0.6	2.3	−1.7
West	1,968	0.6	0.0	−0.9	−2.3	−0.1	0.3	2.3	−0.1
Other	49	−0.3	0.1	−0.9	−2.2	−0.1	0.9	2.3	−0.2
Puerto Rico	41	−0.5	0.1	−0.8	−2.2	−0.1	0.5	2.3	−0.7
Facility Location: Region of the Country (Census Region)									
New England	347	−0.7	0.1	−0.9	−2.1	−0.1	0.3	2.3	−1.1
Mid Atlantic	501	−0.3	−0.1	−0.9	−2.1	−0.1	1.1	2.3	−0.1
East North Central	2,271	0.0	0.1	−0.9	−2.4	−0.1	0.4	2.3	−0.6
West North Central	721	0.0	−0.1	−0.9	−2.3	−0.1	0.6	2.3	−0.5
South Atlantic	1,791	−0.3	−0.1	−0.9	−2.3	−0.1	−0.6	2.3	−2.0
East South Central	426	−0.1	0.0	−0.9	−2.4	−0.1	0.0	2.3	−1.1
West South Central	3,093	0.3	0.0	−0.9	−2.3	−0.1	−0.8	2.3	−1.5
Mountain	672	0.2	0.1	−0.9	−2.3	−0.1	−0.2	2.3	−0.9
Pacific	1,296	0.7	0.0	−0.9	−2.3	−0.1	0.6	2.3	0.3
Facility Size (Number of 1st Episodes)									
<100 episodes	3,177	0.0	0.3	−0.9	−2.3	−0.1	0.4	2.3	−0.3
100 to 249	2,733	0.1	0.2	−0.9	−2.4	−0.1	0.1	2.3	−0.7
250 to 499	2,342	0.1	0.0	−0.9	−2.3	−0.1	0.0	2.3	−0.9
500 to 999	1,597	0.0	0.0	−0.9	−2.3	−0.1	−0.1	2.3	−1.1
1,000 or More	1,318	0.0	−0.1	−0.9	−2.3	−0.1	0.0	2.3	−1.1

Source: CY 2015 Medicare claims data for episodes ending on or before December 31, 2015 (as of December 31, 2015) for which we had a linked OASIS assessment.

[1] The impact of the CY 2017 home health wage index is offset by the wage index budget neutrality factor described in section III.C.3 of this proposed rule.

[2] The impact of the CY 2017 home health case-mix weights reflects the recalibration of the case-mix weights as outlined in section III.B of this proposed rule offset by the case-mix weights budget neutrality factor described in section III.C.3 of this proposed rule.

[3] The 0.97 percent reduction to the national, standardized 60-day episode payment amount in CY 2017 is estimated to have a 0.9 percent impact on overall HH PPS expenditures.

[4] The impact of rebasing includes the rebasing adjustments to the national, standardized 60-day episode payment rate (−2.74 percent after the CY 2017 payment rate was adjusted for the wage index and case-mix weight budget neutrality factors and the nominal case-mix reduction), the national per-visit rates (+2.9 percent), and the NRS conversion factor (−2.82 percent). The estimated impact of the NRS conversion factor rebasing adjustment is an overall -0.01 percent decrease in estimated payments to HHAs

[4] The CY 2017 home health payment update percentage reflects the home health market basket update of 2.8 percent, reduced by a 0.5 percentage point multifactor productivity (MFP) adjustment as required under section 1895(b)(3)(B)(vi)(I) of the Act, as described in section III.C.1 of this proposed rule.

Region Key:
New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont;
Middle Atlantic = Pennsylvania, New Jersey, New York;
South Atlantic = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia;
East North Central = Illinois, Indiana, Michigan, Ohio, Wisconsin;
East South Central = Alabama, Kentucky, Mississippi, Tennessee;
West North Central = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota;
West South Central = Arkansas, Louisiana, Oklahoma, Texas;
Mountain = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming;
Pacific = Alaska, California, Hawaii, Oregon, Washington;
Other = Guam, Puerto Rico, Virgin Islands

2. HHVBP Model

Table 37 displays our analysis of the distribution of possible payment adjustments at the 3-percent, 5-percent, 6-percent, 7-percent, and 8-percent rates that are being used in the Model using the 2013 and 2014 OASIS measures, hospitalization measure and Emergency Department (ED) measure from QIES, and Home Health CAHPS data. The impacts below also account for the proposals to change the smaller-volume cohort size determination, calculate achievement threshold and benchmark proposals at the state level, and revise the applicable measures. We determined the distribution of possible payment adjustments based on ten (10) OASIS quality measures, two (2) claims-based measures in QIES, the three (3)New Measures (with the assumption that all HHAs reported on all New Measures and received full points), and QIES Roll Up File data in the same manner as they would be in the Model. The five (5) HHCAHPS measures are based on archived data. The size of the cohorts were determined using the 2014 Quality Episode File based on OASIS assessments (the Model will use the year before each performance year), whereby the HHAs reported at least five measures with over 20 observations. The basis of the payment adjustment was derived from complete 2014 claims data. We note that this impact analysis is based on the aggregate value of all nine (9) selected states.

Table 38 displays our analysis of the distribution of possible payment adjustments based on the same 2013–2014 data used to calculate Table 37, providing information on the estimated impact of this proposed rule. We note that this impact analysis is based on the aggregate value of all nine (9) selected states. All Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. Value-based incentive payment adjustments for the estimated 1,900 plus HHAs in the selected states that compete in the HHVBP Model are stratified by size as described in this proposed rule. Under the proposal described, there must be a minimum of eight (8) HHAs in any cohort.

Those HHAs that are in states that do not have at least eight small HHAs would not have a smaller-volume cohort and thus there would only be one cohort that would include all the HHAS in that state. As indicated in Table 38, under this proposal, Massachusetts, Maryland, North Carolina, Tennessee and Washington would only have one cohort and Florida, Arizona, Iowa, Nebraska would have a smaller-volume cohort and a larger-volume cohort. For example, Iowa has 29 HHAs eligible to be exempt from being required to have their beneficiaries complete HHCAHPS surveys because they provided HHA services to less than 60 beneficiaries in 2013. Therefore, those 29 HHAs would be competing in Iowa's smaller-volume cohort if the performance year was 2014.

Using 2013–2014 data and the payment adjustment of 5-percent (as applied in CY 2019), based on the ten (10) OASIS quality measures, two (2) claims-based measures in QIES, the five (5) HHCAHPS measures (based on the archived data), and the three (3) New Measures (with the assumption that all HHAs submitted data), Table 38 illustrates that smaller-volume HHAs in Iowa would have a mean payment adjustment of positive 0.62 percent and the payment adjustment ranges from −2.3 percent at the 10th percentile to +3.8 percent at the 90th percentile. As a result of using the OASIS quality and claims-based measures, the same source data (from QIES rather than archived data) that the Model will use for implementation, and adding the assumption that all HHAs will submit data for each of the New Measures when calculating the payment adjustments, the range of payment adjustments for all cohorts in this proposed rule is lower than that was included in HH PPS 2016 rule. This difference is largely due to the lowered variation in TPS caused by the assumption that all HHAs will submit data for each of the New Measures.

Table 39 provides the payment adjustment distribution based on proportion of dually-eligible beneficiaries, average case mix (using HCC scores), proportion that reside in rural areas, as well as HHA organizational status. Besides the observation that higher proportion of dually-eligible beneficiaries serviced is related to better performance, the payment adjustment distribution is consistent with respect to these four categories.

The payment adjustment percentages were calculated at the state and size level so that each HHA's payment adjustment was calculated as it would be in the Model. Hence, the values of each separate analysis in the tables are representative of what they would be if the baseline year was 2013 and the performance year was 2014. There were 1,839 HHAs in the nine selected states out of 1,991 HHAs that were found in the HHA data sources that yielded a sufficient number of measures to receive a payment adjustment in the Model. It is expected that a certain number of HHAs will not be subject to the payment adjustment because they may be servicing too small of a population to report on an adequate number of measures to calculate a TPS.

TABLE 37—HHVBP MODEL: ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES

[Percentage]

Payment adjustment distribution	Range	10%	20%	30%	40%	Median	60%	70%	80%	90%
3% Payment Adjustment For Performance year 1 of the Model	3.08	−1.23	−0.87	−0.56	−0.30	−0.02	0.27	0.61	1.11	1.85
5% Payment Adjustment For Performance year 2 of the Model	5.12	−2.04	−1.45	−0.94	−0.50	−0.03	0.46	1.01	1.85	3.08
6% Payment Adjustment For Performance year 3 of the Model	6.15	−2.45	−1.74	−1.13	−0.61	−0.04	0.55	1.21	2.22	3.70
7% Payment Adjustment For Performance year 4 of the Model	7.18	−2.86	−2.03	−1.32	−0.71	−0.04	0.64	1.42	2.59	4.32
8% Payment Adjustment For Performance year 5 of the Model	8.25	−3.27	−2.32	−1.50	−0.81	−0.05	0.73	1.62	2.96	4.93

TABLE 38—HHVBP MODEL: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT

[Based on a 5-percent payment adjustment]

COHORT	# of HHA	Average payment adj. (%)	10%	20%	30%	40%	Median	60%	70%	80%	90%
HHA Cohort in States with no small cohorts (percent)											
MA	127	0.00	−2.20	−1.50	−1.10	−0.70	−0.30	0.00	0.80	1.40	2.70
MD	53	0.56	−1.50	−1.10	−0.80	−0.10	0.20	0.50	1.40	2.00	3.60
NC	172	0.16	−1.90	−1.50	−1.00	−0.50	0.10	0.50	0.90	1.70	2.40
TN	135	0.36	−2.00	−1.30	−0.80	−0.40	−0.10	0.30	0.90	2.00	3.10
WA	59	0.71	−1.70	−0.70	−0.30	0.20	0.50	0.80	1.70	2.30	2.90
Smaller-volume HHA Cohort in states with small cohort (percent)											
AZ small	9	0.53	−1.20	−0.70	−0.70	−0.50	−0.30	−0.10	0.60	0.90	5.00
FL small	130	−0.14	−2.20	−1.70	−1.20	−0.60	−0.20	0.10	0.40	1.20	1.80
IA small	29	0.62	−2.30	−1.10	−0.80	0.00	0.30	0.90	1.70	2.30	3.80
NE small	16	0.48	−1.70	−1.60	−1.20	−0.60	−0.40	1.30	2.20	2.40	4.00
Larger-volume HHA Cohort in states with small cohorts (percent)											
AZ large	112	−0.06	−2.20	−1.50	−1.10	−0.70	−0.30	0.10	0.50	1.30	2.30
FL large	889	0.37	−2.10	−1.50	−0.90	−0.40	0.00	0.60	1.30	2.20	3.30
IA large	107	−0.21	−2.30	−1.60	−1.30	−0.70	−0.20	0.10	0.50	1.00	1.80
NE large	49	0.31	−1.80	−1.20	−0.90	−0.60	−0.10	0.30	0.70	1.80	3.70

TABLE 39—PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS

[Based on a 5-percent payment adjustment]

COHORT	# of HHA	Average payment adj. (%)	10%	20%	30%	40%	Median	60%	70%	80%	90%
Low % Dually-eligible	621	0.18	−1.80	−1.30	−0.90	−0.50	0.00	0.40	0.90	1.50	2.50
Medium % Dually-eligible	841	−0.15	−2.20	−1.70	−1.20	−0.80	−0.40	0.00	0.50	1.20	2.20
High % Dually-eligible	416	1.21	−1.80	−0.80	−0.20	0.50	1.10	1.80	2.60	3.30	4.20
Low acuity	459	0.97	−1.70	−1.00	−0.40	0.10	0.70	1.30	2.10	2.90	4.00
Mid acuity	1089	0.83	−2.10	−1.50	−1.00	−0.60	−0.10	0.30	0.80	1.50	2.60
High acuity	338	−0.16	−2.10	−1.60	−1.30	−0.90	−0.50	−0.10	0.50	1.30	2.40
All non-rural	989	0.57	−2.10	−1.50	−0.90	−0.40	0.10	1.00	1.80	2.70	3.80
Up to 35% rural	141	0.01	−2.10	−1.50	−1.10	−0.60	−0.20	0.20	0.70	1.40	2.30
Over 35% rural	172	0.54	−1.80	−1.30	−0.90	−0.50	0.00	0.50	1.10	1.70	2.90
Church	62	0.80	−1.70	−0.90	−0.80	0.10	0.40	1.10	1.70	2.60	3.70
Private NP	168	0.22	−1.90	−1.30	−0.90	−0.30	0.10	0.50	0.90	1.70	2.50
Other	84	0.40	−1.60	−1.10	−0.70	−0.40	0.20	0.60	1.00	1.80	2.60
Private FP	1315	0.20	−2.10	−1.50	−1.00	−0.60	−0.10	0.30	1.00	1.90	3.10
Federal	72	0.37	−2.20	−1.60	−1.10	−0.40	0.20	0.60	1.40	2.10	2.80
State	5	−0.39	−2.50	−1.90	−1.40	−0.50	0.30	0.50	0.60	0.80	1.00
Local	57	0.50	−1.50	−1.10	−0.70	0.00	0.30	0.60	0.90	1.40	2.40

D. Alternatives Considered

As described in the CY 2016 HH PPS proposed rule (80 FR 39911), we considered proposing to reduce the national, standardized 60-day episode payment rate by 3.41 percent in CY 2016 to account for nominal case-mix growth between CY 2012 and CY 2014. If we were to reduce the national, standardized 60-day episode payment rate by 3.41 percent, we estimated that the aggregate impact would have been a decrease of $600 million in payments to HHAs. However, instead of implementing a one-time reduction in the national, standardized 60-day episode payment rate of 3.41 percent in CY 2016 to account for nominal case-mix growth from CY 2012 through CY 2014, we finalized a reduction to the national, standardized 60-day episode payment rate of 0.97 percent in CY 2016, CY 2017, and CY 2018 to account for nominal case-mix growth from CY 2012 through CY 2014 (80 FR 68646). Since the 0.97 percent reduction to the national, standardized 60-day episode payment rate to account for nominal case-mix growth from 2012 to 2014 was finalized in the CY 2016 HH PPS final rule, we did not consider alternatives to implementing this reduction for CY 2017.

Section 3131(a) of the Affordable Care Act mandates that starting in CY 2014, the Secretary must apply an adjustment to the national, standardized 60-day episode payment rate and other amounts applicable under section 1895(b)(3)(A)(i)(III) of the Act to reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. In addition, section 3131(a) of the Affordable Care Act mandates that rebasing must be phased-in over a 4-year period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment (2010) under section 1895(b)(3)(A)(i)(III) of the Act, and be fully implemented in CY 2017. Therefore, in the CY 2014 HH PPS final rule (78 FR 77256), we finalized rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor. As we noted in the CY 2014 HH PPS final rule, because section 3131(a) of the Affordable Care Act requires a four year phase-in of rebasing, in equal increments, to start in CY 2014 and be fully implemented in CY 2017, we do not have the discretion to delay, change, or eliminate the rebasing adjustments once we have determined that rebasing is necessary (78 FR 72283).

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2016 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. For CY 2016, section 3401(e) of the Affordable Care Act, requires that, in CY 2015 (and in subsequent calendar years), the market basket update under the HHA prospective payment system, as described in section 1895(b)(3)(B) of the Act, be annually adjusted by changes in economy-wide productivity. Beginning in CY 2015, section 1895(b)(3)(B)(vi)(I) of the Act, as amended by section 3401(e) of the Affordable Care Act, requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the HHA PPS for CY 2015 and each subsequent CY. The −0.5 percentage point productivity adjustment to the proposed CY 2017 home health market basket update (2.8 percent), is discussed in the preamble of this rule and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi)(I) of the Act (as amended by the Affordable Care Act).

With regards to payments made under the HH PPS for high-cost "outlier" episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care), we did not consider maintaining the fixed-dollar loss (FDL) ratio at 0.45 in section III.D.3 of this proposed rule because simulations using CY 2015 utilization data (that is, home health claims data) the proposed CY 2017 HH PPS payment rates resulted in an estimated 2.58 percent of total HH PPS payments being paid as outlier payments using the existing methodology (cost-per-visit) for calculating the cost of an episode of care. Likewise, simulations using CY 2015 utilization data (that is, home health claims data) the proposed CY 2017 HH PPS payment rates resulted in an estimated 3.10 percent of total HH PPS payments being paid as outlier payments using the proposed methodology (cost-per-unit) for calculating the cost of an episode of care. The FDL ratio and the loss-sharing ratio must be selected so that the estimated outlier payments do not exceed the 2.5 percent of total HH PPS payments (as required by section 1895(b)(5)(A) of the Act). We did not consider proposing a change to the loss-sharing ratio (0.80) in order for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.)

With regards to the methodology used to calculate the cost of an episode of care in order to determine the payment amount under the HH PPS for high-cost "outliers" (that is, episodes of care with unusual variations in the type or amount of medically necessary care), in section III.D.2, we considered maintaining the current methodology used to calculate the cost of an episode of care (cost-per-visit). However, due to the findings from the home health study required as a result of section 3131(d) of the Affordable Care Act (as discussed in section III.D.2 of this proposed rule and in the CY 2016 HH PPS proposed rule (80 FR 39864), we believe that the proposed methodology change (cost-per-unit) helps to alleviate financial disincentives for providers to treat medically complex beneficiaries who require longer visits. Since the projection of the percentage of outlier dollars is the same as before the change, the impact of this proposal is budget neutral.

As described in Section III.E of this proposed rule, the Consolidated Appropriations Act of 2016 (Pub. L 114–113) amends both Section 1834 of the Act (42 U.S.C. 1395m) and Section 1861(m)(5) of the Act (42 U.S.C. 1395x(m)(5)), requiring a separate payment to a HHA for an applicable disposable device when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. Therefore, we do not have the discretion to delay or eliminate the implementation of a separate payment amount for NPWT performed using a disposable device and thus we did not consider any alternatives regarding this proposal.

We invite comments on the alternatives discussed in this analysis.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 40, we have prepared an accounting statement showing the classification of the transfers and costs associated with the HH PPS provisions of this proposed rule. Table 40 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this proposed rule for the HH PPS provisions.

TABLE 40—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM THE CYS 2016 TO 2017 *

Category	Transfers
Annualized Monetized Transfers.	−$180 million.
From Whom to Whom?	Federal Government to HHAs.

Table 41 provides our best estimate of the decrease in Medicare payments under the HHVBP Model as a result of the proposed changes presented in this proposed rule for the HHVBP Model.

TABLE 41—ACCOUNTING STATEMENT: HHVBP MODEL CLASSIFICATION OF ESTIMATED COST SAVINGS FOR CY 2016–2021

Category	Savings
6-Year Gross Savings Medicare Payments ..	−$378 million. Hospitals and SNFs.

F. Conclusion

1. HH PPS

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is a decrease of 1.0 percent, or $180 million, in Medicare payments to

HHAs for CY 2017. The −$180 million impact reflects the effects of the 2.3 percent CY 2017 HH payment update percentage ($420 million increase), a 0.9 percent decrease in payments due to the 0.97 percent reduction to the national, standardized 60-day episode payment rate in CY 2016 to account for nominal case-mix growth from 2012 through 2014 ($160 million decrease), the 0.1 percent decrease in payments due to the change to the FDL ratio ($20 million decrease), and a 2.3 percent decrease in in payments due to the third year of the 4-year phase-in of the rebasing adjustments required by section 3131(a) of the Affordable Care Act ($420 million decrease).

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

2. HHVBP Model

In conclusion, we estimate there would be no net impact (to include either a net increase or reduction in payments) in this proposed rule in Medicare payments to HHAs competing in the HHVBP Model for CY 2017. However, the overall economic impact of the HHVBP Model provision is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model. The financial estimates were based on the analysis of hospital, home health and skilled nursing facility claims data from nine states using the most recent 2014 Medicare claims data. A study published in 2002 by the Journal of the American Geriatric Society (JAGS), "Improving patient outcomes of home health care: findings from two demonstration trials of outcome-based quality improvement," formed the basis for CMMI's projections.[127] That study observed a hospitalization relative rate of decline of 22-percent to 26-percent over the 3-year and 4-year demonstration periods (the 1st year of each being the base year) for the national and New York trials. CMMI assumed a conservative savings estimate of up to a 6-percent ultimate annual reduction in hospitalizations and up to a 1.0-percent ultimate annual reduction in SNF admissions and took into account costs incurred from the beneficiary remaining in the HHA if the hospitalization did not occur; resulting in total projected six performance year gross savings of $378 million. Based on the JAGS study, which observed hospitalization reductions of over 20-percent, the 6-percent ultimate annual hospitalization reduction assumptions are considered reasonable.

IX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

List of Subjects

42 CFR part 409

Health facilities, Medicare

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 409.50 is revised to read as follows:

§ 409.50 Coinsurance for durable medical equipment (DME) and applicable disposable devices furnished as a home health service.

The coinsurance liability of the beneficiary or other person for DME or applicable disposable devices (as defined in section 1834(s)(2)) furnished as a home health service is 20 percent of the customary (insofar as reasonable) charge for the services.

PART 484—HOME HEALTH SERVICES

■ 3. The authority citation for part 484 continues to read as follows:

Authority: Secs 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 4. Section 484.240 is amended by revising paragraph (d) to read as follows:

§ 484.240 Methodology used for the calculation of the outlier payment.

* * * * *

(d) CMS imputes the cost for each episode by multiplying the national per-15 minute unit amount of each discipline by the number of 15 minute units in the discipline and computing the total imputed cost for all disciplines.

* * * * *

■ 5. Section 484.305 is amended by revising the definition of "Benchmark" and removing the definition of "Starter Set" and to read as follows:

§ 484.305 Definitions.

* * * * *

Benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline period, calculated for each state.

* * * * *

■ 6. Section 484.315 is amended by revising paragraph (a) to read as follows:

§ 484.315 Data reporting for measures and evaluation under the Home Health Value-Based Purchasing (HHVBP) Model.

(a) Competing home health agencies will be evaluated using a set of quality measures.

* * * * *

§ 484.320 [Amended]

■ 7. Section 484.320 is amended by:

■ a. Amending paragraphs (a), (b), and (c) by removing the phrase "in the starter set,".

■ b. Amending paragraph (d) by removing the phrase "in the starter set".

■ 8. Section 484.335 is added to read as follows:

§ 484.335 Appeals Process for the Home Health Value-Based Purchasing (HHVBP) Model.

(a) *Requests for recalculation*—(1) *Matters for recalculation.* Subject to the limitations on review under section 1115A of the Act, a HHA may submit a request for recalculation under this section if it wishes to dispute the calculation of the following:

(i) Interim performance scores.

(ii) Annual total performance scores.

(iii) Application of the formula to calculate annual payment adjustment percentages.

(2) *Time for filing a request for recalculation.* A recalculation request must be submitted in writing within 15 calendar days after CMS posts the HHA-specific information on the HHVBP Secure Portal, in a time and manner specified by CMS.

(3) *Content of request.* (i) The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).

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[127] Shaughnessy, *et al.* "Improving patient outcomes of home health care: findings from two demonstration trials of outcome-based quality improvement," available at *http://www.ncbi.nlm.nih.gov/pubmed/12164991.*

(ii) The basis for requesting recalculation to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for recalculation.* In conducting the recalculation, CMS will review the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the home health agency. CMS may also review any other evidence it believes to be relevant to the recalculation.

(5) *Recalculation decision.* CMS will issue a written notification of findings. A recalculation decision is subject to the request for reconsideration process in accordance with paragraph (b) of this section.

(b) *Requests for reconsideration*—(1) *Matters for reconsideration.* A home health agency may request reconsideration of the recalculation of the annual total performance score and payment adjustment percentage following a recalculation request submitted under § 484.335(a) or the decision to deny a HHA's recalculation request submitted under paragraph (a) of this section.

(2) *Time for filing a request for reconsideration.* The request for reconsideration must be submitted via the HHVBP Secure Portal within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.

(3) *Content of request.* (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting reconsideration to include the specific quality measure data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for reconsideration.* In conducting the reconsideration review, CMS will review the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact

(5) *Reconsideration decision.* CMS reconsideration officials will issue a written determination.

Dated: June 2, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 23, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–15448 Filed 6–27–16; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 422, et al.

Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 422, 423, and 478

[HHS–2015–49]

RIN 0991–AC02

Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the procedures that the Department of Health and Human Services would follow at the Administrative Law Judge level for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries, enrollees in Medicare Advantage and other Medicare competitive health plans, and enrollees in Medicare prescription drug plans, as well as appeals of Medicare beneficiary enrollment and entitlement determinations, and certain Medicare premium appeals. In addition, this proposed rule would revise procedures that the Department of Health and Human Services would follow at the Centers for Medicare & Medicaid Services (CMS) and the Medicare Appeals Council (Council) levels of appeal for certain matters affecting the Administrative Law Judge level.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. eastern standard time (e.s.t.) on August 29, 2016.

ADDRESSES: In commenting, refer to "HHS–2015–49" at the top of your comments. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. We will not accept comments submitted after the comment period.

You may submit comments in one of two ways (to ensure that we do not receive duplicate copies, please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this proposed rule at *www.regulations.gov.* For new users, you can find instructions on how to find a proposed rule and submit comments under the "Help" tab at *www.regulations.gov.*

If you are submitting comments electronically, we strongly encourage you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Portable Document Format (PDF), we strongly encourage you to convert the PDF to print-to-PDF format or to use some other commonly used searchable text format. Please do not submit the PDF in a scanned or read-only format. Using a print-to-PDF format allows us to electronically search and copy certain portions of your submissions.

2. *U.S. Mail or commercial delivery.* You may send written comments to the following address ONLY: Office of Medicare Hearings and Appeals, Department of Health and Human Services, Attention: HHS–2015–49, 5201 Leesburg Pike, Suite 1300, Falls Church, VA 22041.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

Privacy Note: Because comments will be made available for public viewing in their entirety on the Federal eRulemaking portal, commenters should exercise caution and only include in their comments information that they wish to make publicly available.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Rita Wurm, (410) 786–1139 (for issues related to CMS appeals policies and reopening policies).

Jason Green, (571) 777–2723 (for issues related to Administrative Law Judge appeals policies).

Debbie Nobleman, (202) 565–0139 (for issues related to Council appeals policies).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 4 weeks after publication of a document, at the headquarters of the Office of Medicare Hearings and Appeals, 1700 North Moore Street, Suite 1650, Arlington, Virginia 22209, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (703) 235–0635.

Abbreviations

Because we refer to a number of terms by abbreviation or a shortened form in this proposed rule, we are listing these abbreviations and shortened forms, and their corresponding terms in alphabetical order below:

Act—Social Security Act
ALJ—Administrative Law Judge
APA—Administrative Procedures Act
BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554)
CMS—Centers for Medicare & Medicaid Services
Council—Medicare Appeals Council
DAB—Departmental Appeals Board
HHS—U.S. Department of Health and Human Services
IRE—Independent Review Entity
IRMAA—Income Related Monthly Adjustment Amount
MA—Medicare Advantage
MAO—Medicare Advantage Organization
MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
OIG—HHS Office of Inspector General
OMHA—Office of Medicare Hearings and Appeals
QIC—Qualified Independent Contractor
QIO—Quality Improvement Organization
SSA—Social Security Administration

Section 1557 of the Affordable Care Act

Independent of the standards proposed in this rule, the Department commits to complying with section 1557 of the Affordable Care Act, Public Law 111–148, 124 Stat. 470 (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. HHS issued a proposed rule to implement section 1557, *Nondiscrimination in Health Programs and Activities,* on September 8, 2015. 80 FR 54172. The proposed rule would apply, in part, to health programs and activities administered by the Department.

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VII. Federal Analysis

I. Background

In accordance with provisions of sections 1155, 1852, 1860D–4, 1869, and 1876 of the Act, and their implementing regulations, there are multiple administrative appeal processes for Medicare fee-for-service (Part A and Part B) claim, entitlement and certain premium initial determinations; Medicare Advantage (Part C) and other competitive health plan organization determinations; and Part D plan sponsor coverage determinations and certain premium determinations. The first, and in many instances a second, level of administrative appeal are administered by Medicare contractors, Part D plan sponsors, Medicare Advantage organizations or Medicare plans, or by the SSA. For example, under section 1869 of the Act, the Medicare claims appeal process involves redeterminations conducted by the Medicare Administrative Contractors (which are independent of the staff that made the initial determination) followed by reconsiderations conducted by QICs. However, all of the appeals discussed in this proposed regulation could be appealed to the ALJs at OMHA if the amount in controversy requirement and other requirements are met after these first and/or second levels of appeal.

OMHA, a staff division within the Office of the Secretary of HHS, administers the nationwide ALJ hearing program for Medicare claim, organization and coverage determination, and entitlement and certain premium appeals. If the amount in controversy and other filing requirements are met, a hearing before an ALJ is available following a QIO reconsidered determination under section 1155 of the Act; an SSA or QIC reconsideration, or a request for QIC reconsideration for which a decision is not issued timely and a party requests escalation of the matter under section 1869(b)(1)(A) and (d) of the Act (Part A and Part B appeals); an IRE reconsideration or QIO reconsidered determination under sections 1876(c)(5)(B) or 1852(g)(5) of the Act (Part C and other managed health plan appeals); or an IRE reconsideration under section 1860D–4(h) of the Act (Part D appeals). In addition, under current regulations a review by an ALJ is available following a dismissal of a request for reconsideration, if the amount in controversy and other filing requirements are met.

OMHA provides Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as applicable plans, MAOs, and Medicaid State agencies with a fair and impartial forum to address disagreements regarding: Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors; and determinations related to Medicare beneficiary eligibility and entitlement, Part B late enrollment penalties, and IRMAAs, which apply to Medicare Part B and Part D premiums, made by SSA. Further review of OMHA ALJ decisions, except decisions affirming a dismissal of a request for reconsideration, is available from the Medicare Appeals Council (Council) within the DAB, a staff division within the Office of the Secretary of HHS. Judicial review is then available for Council decisions in Federal courts, if the amount in controversy and other requirements are met.

OMHA ALJs began adjudicating appeals in July 2005, based on section 931 of the MMA, which required the transfer of responsibility for the ALJ hearing level of the Medicare claim and entitlement appeals process from SSA to HHS. New rules at 42 CFR part 405, subpart I and subpart J were also established to implement statutory changes to the Medicare fee-for-service (Part A and Part B) appeals process made by BIPA in 2000 and the MMA in 2003. Among other things, these new rules addressed appeals of reconsiderations made by QICs, which were created by BIPA for the Part A and Part B programs. These rules also apply to appeals of SSA reconsiderations. The statutory changes made by BIPA included a 90-day adjudication time frame for ALJs to adjudicate appeals of QIC reconsiderations beginning on the date that a request for an ALJ hearing is timely filed. The new part 405, subpart I rules were initially proposed in the November 15, 2002 **Federal Register** (67 FR 69312) (2002 Proposed Rule) to implement BIPA, and were subsequently implemented in an interim final rule with comment period, which also set forth new provisions to implement the MMA, in the March 8, 2005 **Federal Register** (70 FR 11420) (2005 Interim Final Rule). Correcting amendments to the 2005 Interim Final Rule were published in the June 30, 2005 **Federal Register** (70 FR 37700) (2005 Correcting Amendment I) and in the August 26, 2005 **Federal Register** (70 FR 50214) (2005 Correcting Amendment II), and the final rule was published in the December 9, 2009 **Federal Register** (74 FR 65296) (2009 Final Rule). Subsequent revisions to part 405, subpart I to implement the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act, Pub. L. 112–242) were published in the February 27, 2015 **Federal Register** (80 FR 10611) (SMART Act Final Rule).

In addition to the part 405, subpart I rules, OMHA applies the rules at 42 CFR part 478, subpart B to individuals' appeals of QIO reconsidered determinations; part 422, subpart M to appeals of IRE reconsiderations or QIO reconsidered determinations under the Medicare Advantage (Part C) and other competitive health plan programs; and part 423, subpart U to appeals of IRE reconsiderations under the Medicare prescription drug (Part D) program.

In recent years, the Medicare appeals process has experienced an unprecedented and sustained increase in the number of appeals. At OMHA, for example, the number of requests for an ALJ hearing or review increased 1,222 percent, from fiscal year (FY) 2009 through FY 2014. The increasing number of requests has strained OMHA's available resources and resulted in delays for appellants to obtain hearings and decisions.

Despite significant gains in OMHA ALJ productivity (in FY 2014, each OMHA ALJ issued, on average, a record 1,048 decisions and an additional 456 dismissals), and CMS and OMHA initiatives to address the increasing number of appeals, the number of requests for an ALJ hearing and requests for reviews of QIC and IRE dismissals continue to exceed OMHA's capacity to adjudicate the requests. As of April 30, 2016, OMHA had over 750,000 pending appeals, while OMHA's adjudication capacity was 77,000 appeals per year, with an additional adjudication capacity of 15,000 appeals per year expected by the end of Fiscal Year 2016.

HHS has a three-prong approach to addressing the increasing number of appeals and the current backlog of claims waiting to be adjudicated at OMHA: (1) Request new resources to invest at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog; (2) take administrative actions to reduce the number of pending appeals and implement new strategies to alleviate the current backlog ; and (3) propose legislative reforms that provide additional funding and new authorities to address the volume of appeals. In this notice of proposed rulemaking, HHS is pursuing the three-prong approach by proposing rules that would expand the pool of available OMHA adjudicators and improve the efficiency of the appeals process by streamlining the processes so less time is spent by adjudicators and parties on repetitive issues and procedural matters.

II. General Provisions of the Proposed Regulations

A. Precedential Final Decisions of the Secretary

Council decisions are binding on the parties to that particular appeal and are the final decisions of the Secretary from which judicial review may be sought under section 205(g) of the Act, in accordance with current §§ 405.1130, 422.612(b), 423.2130, and 478.46(b). As explained in the 2009 Final Rule (74 FR 65307 through 65308), ''binding'' indicates the parties are obligated to abide by the adjudicator's action or decision unless further recourse is available and a party exercises that right. "Final" indicates that no further administrative review of the decision is available and judicial review may be immediately sought.

In 1999, the OIG issued a report entitled "Medicare Administrative Appeals—ALJ Hearing Process" (OEI–04–97–00160) (Sept. 1999) (*http://oig.hhs.gov/oei/reports/oei-04-97-00160.pdf*). In that report, the OIG noted that the DAB respondents voiced strong interest in having precedent setting authority in the Medicare administrative appeals process "to clean-up inconsistencies in the appeals process." The OIG recommended that such a case precedent system be established.

Pursuant to section 931(a) of the MMA, HHS and SSA developed a plan for the transition of the ALJ hearing function for some types of Medicare appeals from SSA to HHS, and addressed the feasibility of precedential authority of DAB decisions. See *Report to Congress: Plan for the Transfer of Responsibility for Medicare Appeals* (Mar. 2004) (*https://www.ssa.gov/legislation/medicare/medicare_appeal_transfer.pdf*). HHS determined that at that time, it was not feasible or appropriate to confer precedential authority on Council decisions, but indicated that it would reevaluate the merits of granting precedential authority to some or all Council decisions after the BIPA and MMA changes to the appeals process were fully implemented.

BIPA and MMA changes to the appeals process have now been fully implemented and we believe it is appropriate to propose that select Council decisions be made precedential to increase consistency in decisions at all levels of appeal for appellants. Proposed § 401.109 would introduce precedential authority to the Medicare claim and entitlement appeals process under part 405, subpart I; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. Proposed § 401.109(a) would grant authority to the Chair of the DAB to designate a final decision of the Secretary issued by the Council as precedential. We believe this would provide appellants with a consistent body of final decisions of the Secretary upon which they could determine whether to seek appeals. It would also assist appeal adjudicators at all levels of appeal by providing clear direction on repetitive legal and policy questions, and in limited circumstances, factual questions. In the limited circumstances in which a precedential decision would apply to a factual question, the decision would be binding where the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the Council issued the precedential final decision.

It is appropriate for the DAB Chair to have the role of designating select Council decisions as precedential. The DAB Chair leads the DAB, which was established in 1973. The DAB has wide jurisdiction over disputes arising under many HHS programs and components, and has issued precedential decisions for many years within several of its areas of jurisdiction. (Examples of DAB jurisdiction may be found at 45 CFR part 16, 42 CFR part 498, 42 CFR part 426, and on the DAB's Web site at *www.hhs.gov/dab*.) The Council has been housed within the DAB as an organization since 1995 and is itself also under the leadership of the DAB Chair. Thus, the DAB Chair brings both expertise in the Medicare claims appeals over which the Council has jurisdiction and experience from the DAB's precedential cases to carrying out the role of designating Council decisions to be precedential. Moreover, having the designation performed by the DAB Chair respects the continued independence of the Council as an adjudicative body by allowing the DAB to determine the effect of its own decisions. Limiting binding precedential effect to selected decisions provides the necessary discretion to designate as precedential those Council decisions in which a significant legal or factual issue was fully developed on the record and thoroughly analyzed. Designation might not be appropriate where an issue was mentioned in the decision as relevant but was not outcome determinative, and therefore may not have been as fully developed as is necessary for precedential decisions or where the issues addressed are not likely to have broad application beyond the particular case.

To help ensure appellants and other stakeholders are aware of Council decisions that are designated as precedential, we are proposing that § 401.109(b) would require notice of precedential decisions to be published in the **Federal Register**, and the decisions themselves would be made available to the public, with necessary precautions taken to remove personally identifiable information that cannot be disclosed without the individual's consent. Designated precedents would be posted on an accessible Web site maintained by HHS. Decisions of the Council would bind all lower-level decision-makers from the date that the decisions are posted on the HHS Web site.

Proposed § 401.109(c) would make these precedential decisions binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on SSA to the extent that SSA components adjudicate matters under the jurisdiction of CMS, in the same manner as CMS Rulings under current § 401.108. That means the precedential decision would be binding on CMS and its contractors in making initial determinations, redeterminations, and reconsiderations, under part 405 subpart I, or equivalent determinations under parts 422 subpart M, 423 subparts M and U, and 478 subpart B; OMHA ALJs and, as proposed in II.B below, attorney adjudicators; the Council in its future decisions; and SSA to the extent that it adjudicates matters under the jurisdiction of CMS. Individual determinations and decisions by CMS contractors, OMHA ALJs, and the Council currently are not precedential and have no binding effect on future initial determinations (and equivalent determinations) or claims appeals. We are not proposing to change the non-precedential status and non-binding effect on future initial determinations (and equivalent determinations) or claim appeals of any determinations or decisions except as to Council decisions designated as precedential by the DAB Chair.

Proposed § 401.109(d) would specify the scope of the precedential effect of a Council decision designated by the DAB Chair. The Council's legal analysis and interpretation of an authority or provision that is binding (see, for example §§ 405.1060 and 405.1063) or owed substantial deference (see, for example § 405.1062) would be binding in future determinations and appeals in which the same authority or provision is applied and is still in effect. However, if CMS revises the authority or provision that is the subject of a precedential decision, the Council's legal analysis and interpretation would not be binding on claims or other disputes to which the revised authority or provision applies. For example, if a Council decision designated as precedential by the DAB Chair interprets a CMS manual instruction, that interpretation would be binding on pending and future appeals and initial determinations to which that manual instruction applies. However, CMS would be free to follow its normal internal process to revise the manual instruction at issue. Once the revised instruction is issued through the CMS process, the revised instruction would apply to making initial determinations on all claims thereafter. This would help ensure that CMS continues to have the ultimate authority to administer the Medicare program and promulgate regulations, and issue sub-regulatory guidance and policies on Medicare coverage and payment.

If the decision is designated as precedential by the DAB Chair, proposed § 401.109(d) would also make the Council's findings of fact binding in future determinations and appeals that involve the same parties and evidence. For example, if a precedential Council decision made findings of fact related to the issue of whether an item qualified as durable medical equipment and the same issue was in dispute in another appeal filed by the same party, and that party submitted the same evidence to support its assertion, the findings of fact in the precedential Council decision would be binding. However, we note that many claim appeals turn on evidence of a beneficiary's condition or care at the time discrete items or services are furnished, and therefore proposed § 401.109 is unlikely to apply to findings of fact in these appeals.

In addition, consistent with proposed § 401.109, we are proposing at § 405.968(b)(1) to add precedential decisions designated by the Chair of the Departmental Appeals Board as an authority that is binding on the QIC. We are also proposing at §§ 405.1063 and 423.2063, which currently cover the applicability of laws, regulations, and CMS Rulings, to add new paragraph (c) to the sections to provide that precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS. Finally, we are proposing to add precedential decisions to the titles of §§ 405.1063 and 423.2063 to reflect the additional topic covered by proposed paragraph (c).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Precedential final decisions of the Secretary" at the beginning of your comment.

B. Attorney Adjudicators

Sections 1155, 1852(g)(5), 1860D–4(h), 1869(b)(1)(A), and 1876(c)(5)(B) provide a right to a hearing to the same extent as provided in section 205(b) by the HHS Secretary for certain appealable decisions by Medicare contractors or SSA, when the amount in controversy and other filing requirements are met. Hearings under these statutory provisions are conducted by OMHA ALJs with delegated authority from the HHS Secretary, in accordance with these sections and the APA.

Under current §§ 405.1038 and 423.2038, OMHA ALJs are also responsible for a portion of the appeals workload that does not require a hearing because a request for an ALJ hearing may also be addressed without conducting a hearing. For example, under §§ 405.1038 and 4423.2038, if the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue, or if all parties agree in writing that they do not wish to appear before the ALJ at a hearing, the ALJ may issue a decision on the record without holding a hearing. Under current §§ 405.1052(a)(1) and 423.2052(a)(1), OMHA ALJs must also address a large number of requests to withdraw requests for ALJ hearings, which appellants often file pursuant to litigation settlements, law enforcement actions, and administrative agreements in which they agree to withdraw appeals and not seek further appeals of resolved claims. In addition, pursuant to §§ 405.1004 and 423.2004, OMHA ALJs review whether a QIC or IRE dismissal was in error. Under these sections, the ALJ reviews the dismissal, but no hearing is required. In FY 2015, OMHA ALJs addressed approximately 370 requests to review whether a QIC or IRE dismissal was in error. Also adding to the ALJs' workload are remands to Medicare contractors for information that can only be provided by CMS or its contractors under current §§ 405.1034(a) and 423.2034(a), and for further case development or information at the direction of the Council. Staff may identify the basis for these remands before an appeal is assigned to an ALJ and a remand order is prepared, but an ALJ must review the appeal and issue the remand order, taking the ALJ's time and attention away from hearings and making decision on the merits of appeals.

Under section 1869(d) of the Act, an ALJ must conduct and conclude a hearing on a decision of a QIC under subsection (c). Subsection (c) of section 1869 of the Act involves the conduct of reconsiderations by QICs. We believe that the statute does not require the action to be taken by an ALJ in cases where there is no QIC reconsideration (for example, where the QIC has issued a dismissal), or in cases of a remand or a withdrawal of a request for an ALJ hearing, and therefore the findings of fact and conclusions of law need not be rendered. ALJ hearings are ideally suited to obtain testimony and other evidence, and hear arguments related to the merits of a claim or other determination on appeal. ALJs are highly qualified to conduct those hearings and make findings of fact and conclusions of law to render a decision in the more complex records presented with a mix of documentary and testimonial evidence. However, well-trained attorneys can perform a review of the administrative record and more efficiently draft the appropriate order for certain actions, such as issuing dismissals based on an appellant's withdrawal of a request for an ALJ hearing, remanding appeals for information or at the direction of the Council, and conducting reviews of QIC and IRE dismissals.

In addition, current §§ 405.1038 and 423.2038 provide mechanisms for deciding cases without an oral hearing, based on the written record. Cases may be decided without an oral hearing when the record supports a finding in favor of the appellant(s) on every issue; all of the parties have waived the oral hearing in writing; or the appellant lives outside of the United States and did not inform the ALJ that he or she wishes to appear, and there are no other parties who wish to appear. In these circumstances, the need for an experienced adjudicator knowledgeable in Medicare coverage and payment law continues, and well-trained attorneys can review the record, identify the issues, and make the necessary findings of fact and conclusions of law when the regulations do not require a hearing to issue a decision in the appealed matter.

To enable OMHA to manage requests for an ALJ hearing and requests for reviews of QIC and IRE dismissals in a more timely manner and increase service to appellants, while preserving access to a hearing before an ALJ in accordance with the statutes, we are proposing to revise rules throughout part 405, subparts I and J; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B, to provide authority that would allow attorney adjudicators to issue decisions when a decision can be issued without an ALJ conducting a hearing under the regulations, dismissals when an appellant withdraws his or her request for an ALJ hearing, and remands for information that can only be provided by CMS or its contractors or at the direction of the Council; as well as to conduct reviews of QIC and IRE dismissals. We also are proposing to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Allowing attorney adjudicators to issue decisions, dismissals, and remands as described above, and to conduct reviews of QIC and IRE dismissals would expand the pool of OMHA adjudicators and allow ALJs to focus on cases going to a hearing, while still providing appellants with quality reviews and decisions, dismissals, and remands. In addition, the rights associated with an appeal adjudicated by an ALJ would extend to any appeal adjudicated by an attorney adjudicator, including any applicable adjudication time frame, escalation option, and/or right of appeal to the Council.

In addition, we note that even if an attorney adjudicator was assigned to adjudicate a request for an ALJ hearing, that hearing request still could be reassigned to an ALJ for an oral hearing if the attorney adjudicator determined that a hearing could be necessary to render a decision. For example, if the parties waived their rights to an oral hearing in writing, allowing a decision to be issued without conducting an oral hearing in accordance with current §§ 405.1038(b)(1) or 423.2038(b)(1), but the attorney adjudicator believed testimony by the appellant or another party would be necessary to decide the appeal, the attorney adjudicator would refer the appeal to an ALJ to determine whether conducting an oral hearing would be necessary to decide the appeal regardless of the waivers, pursuant to current §§ 405.1036(b)(3) or 423.2036(b)(3). We also note that parties to a decision that is issued without an ALJ conducting an oral hearing pursuant to current §§ 405.1038(a) or 423.2038(a) (that is, the decision is favorable to the appellant on every issue and therefore may be issued based on the record alone) continue to have a right to a hearing and a right to examine the evidence on which the decision is based and may pursue that right by requesting a review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision.

To implement this proposal, we are proposing to revise provisions throughout part 405 subpart I, part 422 subpart M, part 423 subparts M and U, and part 478 subpart U, as detailed in proposed revisions to specific sections, in section III of this proposed rule, below. In addition, we are proposing to define an attorney adjudicator in § 405.902, which provides definitions that apply to part 405 subpart I. We are proposing to define an "attorney adjudicator" in § 405.902 as a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance. In addition, we are proposing to indicate in § 405.902 that the attorney adjudicator is authorized to take the actions provided for in subpart I on requests for ALJ hearing and requests for reviews of QIC dismissals. These proposals would provide the public with an understanding of the attorney adjudicator's qualifications and scope of authority, and we also note that attorney adjudicators would receive the same training as OMHA ALJs.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Attorney Adjudicators" at the beginning of your comment.

C. Application of 405 Rules to Other Parts

Current § 422.562(d) states that unless subpart M regarding grievances, organization determinations and appeals under the Medicare Advantage program provides otherwise, the regulations found in part 405 apply under subpart M to the extent appropriate. In addition, current § 422.608, which is a section within subpart M, provides that the regulations under part 405 regarding Council review apply to the subpart to the extent that they are appropriate.

Similar to current § 422.562(d), § 478.40(c) indicates that the part 405 regulations apply to hearings and appeals under subpart B of part 478 regarding QIO reconsiderations and appeals, unless they are inconsistent with specific provisions in subpart B. Thus, the part 405 rules are used, to the extent appropriate, for administrative review and hearing procedures in the absence of specific provisions related to administrative reviews and hearing procedures in part 422, subpart M; and part 478, subpart B, respectively. These general references to part 405 are often helpful in filling in gaps in procedural rules when there is no rule on point in the respective part. However, there has been confusion on the application of part 405 rules when a part 405 rule implements a specific statutory provision that is not in the authorizing statute for the referring subpart and HHS has not adopted a similar policy for the referring subpart in its discretion to administer the Medicare Advantage, QIO, and cost plan appeals programs. For example, certain procedures and provisions of section 1869 of the Act (governing certain determinations and appeals under Medicare Part A and Part B) that are implemented in part 405, subpart I are different than or not addressed in sections 1155 (providing for reconsiderations and appeals of QIO determinations), 1852(g) (providing for appeals of MA organization determinations), and 1876 (providing for appeals of organization determinations made by section 1876 health maintenance organizations (HMOs) and competitive medical plans (CMPs). Section 1869 of the Act provides for, among other things, redeterminations of certain initial determinations, QIC reconsiderations following redeterminations or expedited determinations; ALJ hearings and decisions following a QIC reconsideration; DAB review following ALJ decisions; specific time frames in which to conduct the respective adjudications; and, at certain appeal levels, the option to escalate appeals to the next level of appeal if the adjudication time frames are not met. In addition, section 1869(b)(3) of the Act does not permit providers and suppliers to introduce evidence in an appeal brought under section 1869 of the Act after the QIC reconsideration, unless there is good cause that precluded the introduction of the evidence at or before the QIC reconsideration.

In contrast, sections 1852(g)(5) of the Act and 1876(c)(5)(B) of the Act incorporate some, but not all, of the provisions of section 1869 of the Act, and add certain requirements, such as making the MAO, HMO, or CMP a party to an ALJ hearing. For example, sections 1852(g)(5) and 1876(c)(5)(B) of the Act specifically incorporate section 1869(b)(1)(E)(iii) of the Act to align the amount in controversy requirements for an ALJ hearing and judicial review among the three sections. However, sections 1852(g) and 1876(c)(5)(B) do not incorporate adjudication time frames and escalation provisions, or the limitation on new evidence provision of section 1869(b)(3) of the Act.

Additionally, section 1155 of the Act provides for an individual's right to appeal certain QIO reconsidered determinations made under section 1154 of the Act directly to an ALJ for hearing. However, section 1155 of the Act does not reference section 1869 of the Act or otherwise establish an adjudication time frame, and provides for a different amount in controversy requirement for an ALJ hearing.

Despite these statutory distinctions, HHS has established similar procedures by regulation to the extent practicable, when not addressed by statute. For example, section 1860D–4(h) of the Act, which addresses appeals of coverage determinations under Medicare Part D, incorporates paragraphs (4) and (5) of section 1852(g) of the Act. As discussed above, section 1852(g) does not incorporate adjudication time frames from section 1869 of the Act or otherwise establish such time frames. However, through rulemaking for Part D coverage determination appeals, HHS has adopted a 90-day adjudication time frame for standard requests for an ALJ hearing and requests for Council review of an ALJ decision, as well as a 10-day adjudication time frame when the criteria for an expedited hearing or review are met.

To clarify the application of the part 405 rules, we are proposing revisions to parts 422 and 478. Proposed §§ 422.562(d) and 422.608 would provide that the part 405 rules do not apply when the part 405 rule implements a statutory provision that is not also applicable to section 1852 of the Act. Similarly, proposed § 478.40(c) would provide that the part 405 rules do not apply when the part 405 rule implements a statutory provision that is not also applicable to section 1155 of the Act. In addition, proposed § 478.40(c) removes language that equates an initial determination and reconsidered determination made by a QIO to contractor initial determinations and reconsidered determinations under part 405 because that language has caused confusion with provisions that are specific to part 405 and QIC reconsiderations, and it is not necessary to apply the remaining part 405, subpart I procedural rules in part 478, subpart B proceedings. In addition to clarifying the application of part 405 rules to other parts, these revisions would help ensure that statutory provisions that are specific to certain Medicare appeals are not applied to other appeals without HHS first determining, through rulemaking, whether it would be appropriate to apply a provision and how best to tailor aligning policies for those other appeals.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Application of part 405 rules to other parts" at the beginning of your comment.

D. OMHA References

When the 2005 Interim Final Rule was published in March 2005, implementing the part 405, subpart I rules, OMHA was not yet in operation. Further, processes and procedures were being established under the part 405 subpart I rules, with new CMS contractors and the newly transitioned ALJ hearing function. Since that time, OMHA and CMS and its contractors have developed operating arrangements to help ensure appeals flow between CMS contractors and OMHA, and that appeal instructions for appellants provide clear direction on how and where to file requests for hearings and reviews. However, many of the current rules for the ALJ hearing program that OMHA administers reflect the transition that was occurring at the time of the 2005 Interim Final Rule, and OMHA is not mentioned in the regulation text.

To provide clarity to the public on the role of OMHA in administering the ALJ hearing program, and to clearly identify where requests and other filings should be directed, we are proposing to define OMHA in § 405.902 as the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act. We are also proposing to amend rules throughout part 405, subparts I and J; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. To implement this proposal, we are proposing to revise provisions throughout part 405 subparts I and J, part 422 subpart M, part 423 subparts M and U, and part 478 subpart U, as detailed in proposed revisions to specific sections, in section III of this proposed rule, below.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "OMHA references" at the beginning of your comment.

E. Medicare Appeals Council References

The Council is currently referred to as the "MAC" throughout current part 405, subpart I; part 422, subpart M; and part 423, subparts M and U. This reference has caused confusion in recent years with the transition from Fiscal Intermediaries and Carriers, to Medicare administrative contractors—for which the acronym "MAC" is also commonly used—to process claims and make initial determinations and redeterminations in the Medicare Part A and Part B programs. In addition, current §§ 422.618 and 422.619 reference the Medicare Appeals Council but use "Board" as the shortened reference, and part 478, subpart B, references the DAB as the reviewing entity for appeals of ALJ decisions and dismissals but the Council is the entity that conducts reviews of ALJ decisions and dismissals, and issues final decisions of the Secretary for Medicare appeals under part 478, subpart B.

To address potential confusion with references to Medicare administrative contractors and align references to the Council as the reviewing entity for appeals of ALJ decisions and dismissals throughout part 405, subpart I; part 422, subpart M; and part 423, subparts M and U, we are proposing to amend the following rules to replace "MAC" or "Board" with "Council": §§ 405.902, 405.904, 405.906, 405.908, 405.910, 405.926, 405.980, 405.982, 405.984, 405.990, 405.1026, 405.1036, 405.1037, 405.1042, 405.1046, 405.1048, 405.1050, 405.1052, 405.1054, 405.1060, 405.1063, 405.1062, 405.1100, 405.1102, 405.1104 (as re-designated and revised as proposed § 405.1016(e)–(f)), 405.1106, 405.1108, 405.1110, 405.1112, 405.1114, 405.1116, 405.1118, 405.1120, 405.1122, 405.1124, 405.1126, 405.1128, 405.1130, 405.1132, 405.1134, 405.1136, 405.1138, 405.1140, 422.561, 422.562, 422.608, 422.612, 422.616, 422.618, 422.619, 422.622, 422.626, 423.560, 423.562, 423.1968, 423.1974, 423.1976, 423.1978, 423.1980, 423.1982, 423.1984, 423.1990, 423.2026, 423.2036, 423.2042, 423.2046, 423.2048, 423.2050, 423.2052, 423.2054, 423.2062, 423.2063, 423.2100, 423.2102, 423.2106, 423.2108, 423.2110, 423.2112, 423.2114, 423.2116, 423.2118, 423.2120, 423.2122, 423.2124, 423.2126, 423.2128, 423.2130, 423.2134, 423.2136, 423.2138, and 423.2140.

In addition, to align references to the Council as the reviewing entity for appeals of ALJ decisions and dismissals in part 478, subpart B, we are proposing to amend §§ 478.46 and 478.48 to replace "Departmental Appeals Board" and "DAB," with "Medicare Appeals Council" and "Council".

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Medicare Appeals Council references" at the beginning of your comment.

III. Specific Provisions of the Proposed Rule

A. Provisions of Part 405, Subpart I and Part 423, Subparts M and U

1. Overview

Part 405, subpart I and part 423, subpart U contain detailed procedures for requesting and adjudicating a request for an ALJ hearing, and a request for a review of a QIC or IRE dismissal. Part 423, subpart U provisions were proposed in the March 17, 2008 **Federal**

Register (73 FR 14342) and made final in the December 9, 2009 **Federal Register** (74 FR 65340), and generally follow the part 405, subpart I procedures. In this proposed rule, we generally discuss proposals related to part 405, subpart I, and then whether any aligning revisions to part 423, subpart U, are proposed, unless a provision is specific to Part 405 and there is no corresponding part 423 provision.

2. General Provisions, Reconsiderations, Reopenings, and Expedited Access to Judicial Review

a. Part 423, Subpart M General Provisions (§ 423.562)

Current § 423.562(b)(4) lists the appeal rights of a Part D plan enrollee, if the enrollee is dissatisfied with any part of a coverage determination. Specifically, paragraph (b)(4)(v) describes the right to request Council review of the ALJ's hearing decision if the ALJ affirms the IRE's adverse coverage determination in whole or in part, and paragraph (b)(4)(vi) describes the right to judicial review of the hearing decision if the Council affirms the ALJ's adverse coverage determination in whole or in part, and the amount in controversy requirements are met. We are proposing to revise paragraph (b)(4)(v) to insert "or attorney adjudicator" after each instance of "the ALJ." This proposal is necessary to implement the proposal to allow attorneys to adjudicate requests for an ALJ hearing when no hearing is conducted as proposed in section II.B above, by stating the right to request Council review of an attorney adjudicator decision that affirms the IRE's adverse coverage determination. We also are proposing to remove "hearing" before "decision" in paragraph (b)(4)(v) to reflect that an attorney adjudicator issues decisions without conducting a hearing, and an ALJ may issue a decision without conducting a hearing.

In paragraph (b)(4)(vi), we are proposing to remove "ALJ's" and insert "ALJ's or attorney adjudicator's" in its place to implement the proposal to allow attorneys to adjudicate requests for an ALJ hearing when no hearing is conducted as proposed in section II.B above, by including an attorney adjudicator's decision as a decision that may be affirmed by the Council. We also are proposing to remove "hearing" before "decision" in paragraph (b)(4)(vi) because while the Council may conduct a hearing, Council decisions are generally issued without conducting a hearing, and the decision of the Council is subject to judicial review.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Part 423, subpart M general provisions" at the beginning of your comment.

b. Part 423, Subpart U Title and Scope (§ 423.1968)

The current heading of part 423, subpart U references ALJ hearings but does not reference decisions. We are proposing to revise the heading by replacing "ALJ Hearings" with "ALJ hearings and ALJ and attorney adjudicator decisions" to reflect that subpart U covers decisions by ALJs and attorney adjudicators, as proposed in section II.B above.

Current § 423.1968 explains the scope of the requirements in subpart U. We are proposing at § 423.1968 to expand the scope of subpart U to include actions by attorney adjudicators, as proposed in section II.B above. Specifically, we are proposing at § 423.1968(a) to add that subpart U sets forth requirements relating to attorney adjudicators with respect to reopenings; at § 423.1968(b) to add that subpart U sets forth requirements relating to ALJ decisions and decisions of attorney adjudicators if no hearing is conducted; and at § 423.1968(d) to add that subpart U sets forth the requirements relating to Part D enrollees' rights with respect to ALJ hearings and ALJ or attorney adjudicator reviews. These changes would be necessary to accurately describe the scope of the revised provisions of subpart U to implement the attorney adjudicator proposal discussed in section II.B above.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Part 423, subpart U title and scope" at the beginning of your comment.

c. Medicare Initial Determinations, Redeterminations and Appeals General Description (§ 405.904)

Section 405.904(a) provides a general overview of the entitlement and claim appeals process to which part 405, subpart I applies. Current paragraphs (a)(1) and (a)(2) provide that if a beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, the beneficiary may request that the Council review the case. To provide for the possibility that a decision may be issued without conducting a hearing by an ALJ, as permitted under current rules, or an attorney adjudicator, as proposed in II.B above, we are proposing to add language in paragraphs (a)(1) and (a)(2) to provide that if the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator when no hearing is conducted, the beneficiary may request that the Council review the case. This proposal would provide a comprehensive overview of the entitlement and claim appeals process, with information on the potential for and right to appeal decisions by ALJs when no hearing is conducted, and the right to appeal decisions by attorney adjudicators, if the attorney adjudicator proposals are made final.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption "Medicare initial determinations, redeterminations and appeals general description" at the beginning of your comment.

d. Parties to the Initial Determinations, Redeterminations, Reconsiderations, Proceedings on a Request for Hearing, and Council Review (§ 405.906)

Current § 405.906 discusses parties to the appeals process and subsection (b) currently addresses parties to the redetermination, reconsideration, hearing and MAC. We are proposing in the paragraph heading and introductory text to subsection (b) to replace the phrases "hearing and MAC" and "hearing, and MAC review," respectively, with "proceedings on a request for hearing, and Council review" because, absent an assignment of appeal rights, the parties are parties to all of the proceedings on a request for hearing, including the hearing if one is conducted, and they are parties to the Council's review.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption "Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews" at the beginning of your comment.

e. Medicaid State Agencies (§ 405.908)

Current § 405.908 discusses the role of Medicaid State agencies in the appeals process and states that if a State agency files a request for redetermination, it may retain party status at the QIC, ALJ, MAC and judicial review levels. We are proposing to replace "ALJ" with "OMHA" to provide that the State agency has party status regardless of the adjudicator assigned to the State agency's request for an ALJ hearing or request for review of a QIC dismissal at the OMHA level of review, as attorney adjudicators may issue decisions on requests for hearing and adjudicate requests for reviews of QIC dismissals, as proposed in section II.B above.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption "Medicaid State agencies" at the beginning of your comment.

f. Appointed Representatives (§ 405.910)

The 2002 Proposed Rule (67 FR 69318 through 69319) explained that the § 405.910 requirements for a valid appointment of a representative are necessary to help ensure that adjudicators are sharing and disseminating confidential information with the appropriate individuals. The 2005 Interim Final Rule (70 FR 11428 through 11431) adopted a general requirement to include a beneficiary's health insurance claim number (HICN) for a valid appointment of a representative in § 405.910(c)(5). The SMART Act Final Rule (80 FR 10614, 10617) revised § 405.910(c)(5) to explicitly limit the requirement to include a beneficiary's HICN to instances in which the beneficiary is the party appointing a representative. However, the Medicare manual provision for completing a valid appointment of representative (Medicare Claims Processing Manual (Internet-Only Manual 100–4), chapter 29, § 270.1.2) details the requirements for an appointment of representation to contain a unique identifier of the party being represented. Specifically, if the party being represented is the beneficiary, the Medicare number must be provided, and if the party being represented is a provider or supplier, the National Provider Identifier (NPI) number should be provided. Additionally, the official form for executing a valid appointment of representative (form CMS–1696, available at *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1696.pdf*) provides a blank space for the party to include a Medicare or NPI number. To assist adjudicators in sharing and disseminating confidential information only with appropriate individuals, we are proposing to revise § 405.910(c)(5) to add a requirement to include the Medicare NPI of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative. We are retaining the requirement to identify the beneficiary's Medicare HICN when the beneficiary is the party appointing a representative.

Current § 405.910 also addresses defective appointments, and delegations and revocations of appointments. However, there has been confusion on the effects on the adjudication of an appeal when a defective appointment must be addressed, or when an adjudicator is not timely informed of a delegation or revocation of an appointment. To address the effect of a defective appointment on the adjudication of an appeal to which an adjudication time frame applies, we are proposing to add § 405.910(d)(3), which would extend an applicable adjudication time frame from the later of (1) the date that a defective appointment of representative was filed or (2) the date the current appeal request was filed by the prospective appointed representative, to the date that the defect in the appointment was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative. We are proposing this revision because, in accordance with current § 405.910(d)(1) and (d)(2), a prospective appointed representative lacks the authority to act on behalf of a party and is not entitled to obtain or receive any information related to the appeal. Thus, contact with the party may be necessary to obtain missing information from the appointment, which may delay adjudicating the appeal until the appointment is cured or the party decides to proceed with the appeal without a representative. However, we are proposing that if the request was filed by a prospective appointed representative, the request would be considered filed for the purpose of determining timeliness of the request, even if the individual is not the appointed representative after the appointment is cured, or the party decides to proceed with the appeal without a representative.

We are also proposing at § 405.910(f)(1) to replace "ALJ level" with "OMHA level" so there is no confusion that proceedings at the OMHA level are considered proceedings before the Secretary for purposes of appointed representative fees, regardless of whether the case is assigned to an ALJ or attorney adjudicator.

Current § 405.910(i)(2) and (i)(3) provide that if an appeal involves an appointed representative, an ALJ sends notices of actions or appeal decisions, and requests for information or evidence regarding a claim that is appealed to the appointed representative. We are proposing to insert "or attorney adjudicator" after "ALJ" in § 405.910(i)(2) and (i)(3). This proposal would provide that attorney adjudicators (as proposed in section II.B above), like an ALJ under the current provisions, would send notices of actions or appeal decisions, and requests for information or evidence regarding a claim that is appealed to the appointed representative.

A representative and/or the represented party is responsible for keeping the adjudicator of a pending appeal current on the status of the representative. In practice, sometimes adjudicators are not informed of a delegation or revocation of an appointment of representative that has been filed for an appeal, which results in confusion and potentially duplicative or unnecessary proceedings. We are proposing to revise § 405.910(l)(2) (which, as described later, we are proposing to re-designate as (l)(1)(ii)) to add that a delegation is not effective until the adjudicator receives a copy of the party's written acceptance of the delegation, unless the representative and designee are attorneys in the same law firm or organization, in which case the written notice to the party of the delegation may be submitted if the acceptance is not obtained from the party. This proposed revision would emphasize the importance of keeping adjudicators current on the status of the representative and also state the effects of failing to do so. Proposed § 405.910(l)(2) also serves to assist adjudicators in sharing and disseminating confidential information only with appropriate individuals, and to provide adjudicators with appropriate contact information for scheduling purposes. To accommodate proposed paragraph (l)(2), current paragraph (l), except for the title of the paragraph, would be re-designated as paragraph (l)(1), and the current subparagraphs would also be re-designated accordingly. In addition, we are proposing to add a missing "by" in current paragraph (l)(1)(ii) (re-designated as (l)(1)(i)) of § 405.910 to indicate that a designee accepts to be obligated "by" and comply with the requirements of representation. We are also proposing to revise language in current paragraph (l)(2) (re-designated as (1)(l)(ii)) of § 405.910 to clarify that "this signed statement" refers to the "written statement signed by the party," and the written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice of intent to delegate under paragraph (l)(1)(i) indicates that fact. To further emphasize the importance of keeping adjudicators current on the status of the representative and clarify the effects of failing to do so, we are also proposing to add § 405.910(l)(3) and (m)(4) that a party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated or revoked, respectively, is not good cause for missing a deadline or not appearing at a hearing.

We are not proposing any changes for part 423, subpart U because it does not have a corresponding provision for representative appointments.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Appointed representatives" at the beginning of your comment.

g. Actions That Are Not Initial Determinations (§ 405.926)

Current § 405.926(l) provides that an ALJ's decision to reopen or not to reopen a decision is not an initial determination, and in accordance with the introductory language of § 405.926, is therefore not appealable under subpart I. In section III.A.2.l below, we are proposing to revise the reopening rules to provide that attorney adjudicators would have the authority to reopen their decisions to the same extent that ALJs may reopen their decisions under the current provisions. We are proposing to insert "or attorney adjudicator's" after "ALJ's" in § 405.926(l) to provide that the attorney adjudicator's decision to reopen a decision also is an action that is not an initial determination and therefore not an appealable action under subpart I.

Current § 405.926(m) provides that a determination that CMS or its contractors may participate in or act as parties in an ALJ hearing is not an initial determination, and in accordance with the introductory language of § 405.926, is therefore not appealable under subpart I. As explained in section III.A.3.f below, we are proposing to revise § 405.1010, which currently discusses when CMS or a contractor may participate in an ALJ hearing. As explained in the proposal to revise § 405.1010, CMS or a contractor may elect to participate in the proceedings on a request for an ALJ hearing for which no hearing is conducted, in addition to participating in an ALJ hearing as a non-party participant. To align with our proposed revision to § 405.1010, we are proposing to revise § 405.926(m) to indicate that CMS or its contractors may participate in the full scope of the proceedings on a request for an ALJ hearing, including the hearing, by replacing "participate in or act as parties in an ALJ hearing," with "participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing."

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Actions that are not initial determinations" at the beginning of your comment.

h. Notice of a Redetermination (§ 405.956)

Current § 405.956(b)(8) requires that the notice of a redetermination include a statement that evidence not submitted to the QIC is not considered at an ALJ hearing or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously. We are proposing to remove "an ALJ hearing" and add "the OMHA level" in its place so that the notice of a redetermination is clear that, absent good cause and subject to the exception in § 405.956(d) for beneficiaries not represented by a provider or supplier, evidence that was not submitted to the QIC is not considered by an ALJ or an attorney adjudicator, as defined in Section II.B above.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption "Notice of a redetermination" at the beginning of your comment.

i. Time Frame for Making a Reconsideration Following a Contractor Redetermination, Withdrawal or Dismissal of a Request for Reconsideration, and Reconsideration (§§ 405.970, 405.972, and 405.974)

As discussed in the 2005 Interim Final Rule (70 FR 11444 through 11445) and the 2009 Final Rule (74 FR 65311 through 65312), HHS adopted a policy of providing for one level of administrative review of a dismissal of a request for appeal. As a result, an adjudicator's decision or dismissal when reviewing a dismissal action issued at the previous level is binding and not subject to further review. The policy balances a party's need for review and the need for administrative finality. The policy is embodied in the rules relating to reviews of dismissals at the next adjudicative level in current §§ 405.972(e), 405.974(b)(3), 405.1004(c), 405.1102(c), 405.1108(b), and 405.1116.

At the QIC level of appeal, a review of a contractor redetermination and a review of a contractor's dismissal of a request for a redetermination are both characterized as a "reconsideration." While the outcome of a QIC's reconsideration of a contractor dismissal is differentiated and further reviews are not permitted in accordance with current § 405.974(b)(3), an ambiguity exists with regard to the time frame for completing this type of reconsideration and escalation options when that time frame is not met. Current § 405.970 establishes the time frame for making a reconsideration without further qualification. However, section 1869(b)(1)(D)(i) of the Act establishes that a right to a reconsideration of an initial determination (which includes a redetermination under section 1869(a)(3)(D) of the Act) exists if a timely request for a reconsideration is filed within 180 days following receipt of a contractor's redetermination, which is discussed in current § 405.962. In contrast, current § 405.974(b)(1) requires that a request for a QIC reconsideration of a contractor's dismissal of a request for redetermination must be filed within 60 calendar days after receiving the contractor's notice of dismissal. Section 1869 of the Act does not address dismissals. Rather, section 1869(c)(3)(C)(i) and (c)(3)(C)(ii) of the Act only provide for a time frame to complete a reconsideration of an initial determination, and an option to escalate a case if that time frame is not met.

The effect of the ambiguity in current § 405.970 is the potential escalation of a request for a QIC reconsideration of a contractor's dismissal when the reconsideration is not completed within 60 calendar days of a timely filed request for a reconsideration of the dismissal, and a potential hearing being required in accordance with current § 405.1002(b). The potential effect of this ambiguity is contrary to the policy of limiting reviews of dismissals to the next adjudicative level of administrative appeal, as well as the statutory construct for providing ALJ hearings after QIC reconsiderations of redeterminations, or escalations of requests for reconsiderations following a redetermination. We also note that in the parallel context of an ALJ review of a QIC's dismissal of a request for reconsideration, current §§ 405.1002 and 405.1004 establish a clear distinction between a request for hearing following a QIC reconsideration and a request for a review of a QIC dismissal, and current §§ 405.1016 and 405.1104 address the adjudication time frames for ALJ decisions, and the option to escalate an appeal to the Council when a time frame is not met, only in the context of a request for hearing, in accordance with section 1869(d)(1) and (d)(3)(A) of the Act.

To address this unintended outcome of current § 405.970, we are proposing to amend the title of § 405.970 and paragraphs (a), (b)(1), (b)(2), (b)(3), (c), (e)(1), and (e)(2)(i) to provide that the provisions would only apply to a request for a reconsideration following a contractor redetermination, and not to a request for QIC review of a contractor's dismissal of a request for redetermination. These proposed revisions would further our policy on reviews of dismissals and help appellants better understand what may be escalated to OMHA for an ALJ hearing. We are also proposing to replace "the ALJ hearing office" in current paragraph (e)(2)(ii) with "OMHA" because the QIC sends case files for escalated cases to a centralized location, not to individual field offices. We did not propose any parallel changes for part 423 because subpart U does not address IRE reconsiderations and subpart M does not have a provision with the same ambiguity.

To provide additional clarity to the procedures for reviews of dismissal actions we are also proposing to amend the text in §§ 405.972(b)(3), (e) and 405.974(b)(3), and the introductory text of § 405.974(b) to replace the references to a "reconsideration" of a contractor's dismissal of a request for redetermination with the word "review" so that the QIC's action is referred to as a review of a contractor's dismissal of a request for redetermination. We are also proposing to revise the section heading of § 405.972 to read "Withdrawal or dismissal of a request for reconsideration or review of a contractor's dismissal of a request for redetermination" and the section heading of § 405.974 to read, "Reconsideration and review of a contractor's dismissal of a request for redetermination." These proposed revisions are consistent with the description of a reconsideration in section 1869(c)(3)(B)(i) of the Act and § 405.968(a). A QIC's review of a contractor dismissal action is limited to the appropriateness of the dismissal action and does not consist of a review of the initial determination and redetermination, which is the meaning attributed to a reconsideration. In reviewing a contractor dismissal action, the QIC either affirms or vacates the dismissal of the request for redetermination. If a dismissal action is vacated, the appeal is remanded back to the MAC to conduct a redetermination on the merits (§ 405.974).

Current § 405.972(e) provides that a QIC's dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ under § 405.1004. As discussed in section II.B above, we are proposing that an attorney adjudicator may conduct a review of a QIC's dismissal of a request for reconsideration and in section III.A.3.c below, we are proposing to revise § 405.1004 to provide the effect of an attorney adjudicator's action taken in reviewing the QIC dismissal is equivalent to the effect of an ALJ's action taken in reviewing the QIC dismissal. To align with our proposed revision to § 405.1004, we are proposing to insert "or attorney adjudicator" after "an ALJ" in § 405.972(e) to indicate that a QIC's dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ or attorney adjudicator under § 405.1004.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Time frame for making a reconsideration following a contractor redetermination, withdrawal or dismissal of a request for reconsideration, and reconsideration" at the beginning of your comment.

j. Notice of Reconsideration (§ 405.976)

Section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the reconsideration conducted by a QIC unless there is good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. Under this authority, current § 405.976(b)(5)(ii) provides that a notice of reconsideration must include a summary of the rationale for the reconsideration that specifies that all evidence that is not submitted prior to the issuance of the reconsideration will not be considered at the ALJ level, or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration; however, it does not apply to a beneficiary unless the beneficiary is represented by a provider or supplier or to state Medicaid agencies. The statement that the evidence will not be made part of the administrative record is inconsistent with our practice of making a complete record of the administrative proceedings for further reviews, including documents submitted by parties that were not considered in making the decision. Current § 405.1028(c) states that if good cause does not exist, the ALJ must exclude the evidence from the proceedings and may not consider it in reaching a decision. However, it does not instruct the ALJ to remove the evidence from the administrative record, and to do so would preclude an effective review of the good cause determination. In addition, we noted in the 2005 Interim Final Rule (70 FR 11464) that under current § 405.1042(a)(2), excluded evidence is part of the record because it states that in the record, the ALJ must also discuss any evidence excluded under § 405.1028 and include a justification for excluding the evidence. To help ensure that the evidence is preserved in the administrative record, we are proposing to delete "or made part of the administrative record" from the paragraph in § 405.976(b)(5)(ii).

Current § 405.976(b)(7) requires that the QIC notice of reconsideration contain a statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable. As further discussed in section III.A.3.d below, we are proposing revisions to § 405.976(b)(7) along with revisions to the methodology for calculating the amount in controversy required for an ALJ hearing under § 405.1006(d) to better align the amount in controversy with the actual amount in dispute. Please refer to section III.A.3.d for a discussion of these proposals.

We are not proposing any changes to part 423 because subpart U does not address IRE reconsiderations and subpart M does not contain similar provisions.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption "Notice of reconsideration" at the beginning of your comment.

k. Effect of a Reconsideration (§ 405.978)

Current § 405.978 discusses the effect of a QIC reconsideration, and states that a reconsideration is binding on all parties unless, among other things, an ALJ decision is issued in accordance to a request for an ALJ hearing made in accordance with § 405.1014. As discussed in section II.B above, we are proposing that an attorney adjudicator may issue a decision on a request for an ALJ hearing when a hearing is not conducted, and in section III.A.3.v below, we are proposing to revise § 405.1048 to provide the effect of an attorney adjudicator's decision is equivalent to the effect of an ALJ's decision. To align with our proposals to provide that an attorney adjudicator may issue a decision on a request for an ALJ hearing when a hearing is not conducted and the effect of that decision is equivalent to the effect of an ALJ's decision, we are proposing to insert "or attorney adjudicator" after the first use of "ALJ" in § 405.978(a) to indicate that a QIC reconsideration is binding on all parties unless, among other things, an ALJ or attorney adjudicator decision is issued in accordance to a request for an ALJ hearing made in accordance with § 405.1014.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption "Effect of a reconsideration" at the beginning of your comment.

l. Reopenings (§§ 405.980, 405.982, 405.984, 423.1978, 423.1980, 423.1982, and 423.1984)

Sections 405.980 and 423.1980 set forth the rules governing reopening and revision of initial determinations, redeterminations, reconsiderations, decisions, and reviews; §§ 405.982 and 423.1982 set forth the rules governing notice of a revised determination or decision; and §§ 405.984 and 423.1984 set forth the rules on the effect of a revised determination or decision. Pursuant to current §§ 405.1038 and 423.2038, an ALJ may issue a decision on a request for hearing without conducting a hearing in specified circumstances. As proposed in section II.B above, an attorney adjudicator also would be able to issue decisions on requests for an ALJ hearing in specified circumstances, issue dismissals when a party withdraws a request for hearing, and issue decisions on requests to review QIC or IRE dismissals.

We are proposing to insert "or attorney adjudicator" or "attorney adjudicator's," after "ALJ" or "ALJ's" in §§ 405.980(a)(1)(iii), (a)(4), (a)(5), (d) introductory text, (d)(2), (e)(2); 405.982(a), (b); 405.984(d); 423.1980(a)(1)(iii), (a)(4), (d) introductory text, (d)(2), (e)(2); 423.1982(a), (a)(1), (a)(2), (b), (b)(1), and (b)(2); 423.1984(d); 423.1978(a); 423.1980(a)(2). These proposals would provide that decisions issued by attorney adjudicators, as proposed in section II.B above, may be reopened in the same manner as decisions issued by an ALJ (that is, when there is good cause in accordance with §§ 405.986 or 423.1986, or the decision was procured by fraud or similar fault), and with the same limitations, requirements, and effects as reopening an ALJ decision. We believe it is necessary for an attorney adjudicator or the Council to have the authority to reopen the attorney adjudicator's decision on the same bases as an ALJ or the Council may reopen the ALJ's decision under the current rules; to address instances in which there is good cause to reopen the attorney adjudicator's decision (in accordance with §§ 405.986 or 423.1986) or the attorney adjudicator's decision was procured by fraud or similar fault; and the action should be subject to the same limitations and requirements, and have the same effects as an ALJ's action under the provisions.

We are also proposing to replace "hearing decision," "hearing decisions," or "hearings," with "decision" or "decisions" in the titles of current §§ 405.980 and 423.1980; §§ 405.980(a)(1)(iii), (d) introductory text, (d)(2), (e) introductory text, and (e)(2); 423.1980(a)(1)(iii), (d) introductory text, (d)(2), (e) introductory text, and (e)(2); to replace "hearing" with "ALJ or attorney adjudicator decision" in §§ 405.980(a)(1)(iv), (a)(4), (e)(2); 423.1980(a)(1)(iv), (a)(2), and (e)(2); and to replace "ALJ hearing decisions" and "hearing decision," with "ALJ or attorney adjudicator decisions" and "ALJ or attorney adjudicator decision", respectively, in §§ 405.984(d) and 423.1984(d). These proposals would avoid any confusion that reopening under these provisions is limited to decisions for which an oral hearing was conducted, whether the decision is issued by an ALJ without conducting a hearing, as permitted under current rules or by an attorney adjudicator without conducting a hearing, as proposed in section II.B above.

In addition, we are proposing to add in §§ 405.980(a)(1)(iii), (d)(2), (e)(2), and 423.1980(a)(1)(iii), (d)(2), (e)(2) that an ALJ, or attorney adjudicator as proposed in section II.B above, revises "his or her" decision and may reopen "his or her" decision, which reflects our current policy that the deciding ALJ may reopen his or her decision, and avoids any potential confusion that an ALJ or attorney adjudicator may reopen the decision of another ALJ or attorney adjudicator. We are also proposing to insert "its" before "review" in §§ 405.980(a)(1)(iv) and 423.1980(a)(1)(iv) to indicate that the Council's review decision may only be reopened by the Council, to differentiate it from an ALJ or attorney adjudicator decision that the Council may also reopen. In addition, we are proposing to specify in §§ 405.980(d)(2) and (e)(2), and 423.1980(d)(2) and (e)(2) that the Council may reopen "an ALJ or attorney adjudicator" decision consistent with the current policy that the Council may reopen an ALJ decision, and to differentiate the provisions from §§ 405.980(d)(3) and (e)(3), and 423.1980(d)(3) and (e)(3), which provide for the Council to reopen its review decision. We also propose in § 405.980(e)(3) to insert "Council" before "review" to clarify that a party to a Council review may request that the Council reopen its decision.

Finally, we are proposing at § 405.984(c) to replace "in accordance with § 405.1000 through § 405.1064" with "in accordance with § 405.1000 through § 405.1063" to account for the proposed removal of § 405.1064 discussed below.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Reopenings" at the beginning of your comment.

m. Expedited Access to Judicial Review (§§ 405.990 and 423.1990)

Sections 405.990 and 423.1990 set forth the procedures governing expedited access to judicial review (EAJR). Current §§ 405.990(d) and 423.1990(d) allow a requesting party to file an EAJR request with an ALJ or the Council, which is then responsible for forwarding the request to the EAJR review entity within 5 calendar days of receipt. In accordance with current §§ 405.990(f) and 423.1990(e), a request for EAJR must be acted upon by the EAJR review entity within 60 calendar days after the date that the review entity receives a request and accompanying documents and materials. In practice, this process has resulted in confusion and delays for requesting parties when EAJR requests are sent directly to an ALJ or the Council. To simplify the process for requesting parties and to help ensure the timely processing of EAJR requests, we are proposing to revise §§ 405.990(d)(1) and 423.1990(d)(1) to direct EAJR requests to the DAB, which administers the EAJR process. Specifically, we are proposing at §§ 405.990(d)(1)(i) and (ii), and 423.1990(d)(1)(i) and (ii) that the requestor or enrollee may file a written EAJR request with the DAB with the request for ALJ hearing or Council review if a request for ALJ hearing or Council review is not pending, or file a written EAJR request with the DAB if an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council. We are also proposing to revise §§ 405.990(i)(1) and (2) and 423.1990(h)(1) and (2) so that the review entity would forward a rejected EAJR request to OMHA or the Council instead of an ALJ hearing office or the Council, to align with the revised EAJR filing process in which a request for ALJ hearing is submitted to the DAB with an EAJR request; this would also help ensure OMHA can process the request for an ALJ hearing as quickly as possible in the event an EAJR request is rejected.

Current §§ 405.990(i)(2) and 423.1990(h)(2) provide that a 90 calendar day time frame will apply to an appeal when a rejected EAJR request is received by the hearing office or the Council. Current § 405.990(b)(1)(ii) states that an EAJR request may be filed when a request for a QIC reconsideration has been escalated for an ALJ hearing, and in accordance with current § 405.1016(c), a 180 calendar day time frame will apply in that circumstance. In addition, current §§ 405.1036(d) and 423.2036(d) allow an appellant or enrollee to waive the adjudication period for an ALJ to issue a decision specified in §§ 405.1016 and 405.2016, respectively, at any time during the hearing process. To address the possibility that a time frame other than 90 calendar days applies to an appeal, or no adjudication time frame applies to an appeal, we are proposing to revise §§ 405.990(i)(2) and 423.1990(h)(2) to remove the reference to 90 calendar days and provide that if an adjudication time frame applies to an appeal, the adjudication time frame begins on the day the request for hearing is received by OMHA or the request for review is received by the Council, from the EAJR review entity.

In addition, proposed § 405.990(i)(1) would remove the redundant "request" after "EAJR request" in current paragraph (i)(1), which was a drafting error; and proposed § 423.1990(b)(1)(i) would remove "final" before referring to a decision, dismissal, or remand order of the ALJ or attorney adjudicator, as proposed in section II.B above, because as we explained in the 2009 Final Rule (74 FR 65307 through 65308), final decisions of the Secretary are those for which judicial review may be immediately sought under section 205(g) of the Act and the use of "final" in current § 423.1990(b)(1)(i) may cause confusion with such a final decision.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Expedited access to judicial review" at the beginning of your comment.

3. ALJ Hearings

a. Hearing Before an ALJ and Decision by an ALJ or Attorney Adjudicator: General Rule (§§ 405.1000 and 423.2000)

Current §§ 405.1000 and 423.2000 provide a general overview and rules for hearings before an ALJ and decisions on requests for hearings. We are proposing to revise §§ 405.1000(d), (e), (g); and 423.2000(d), (e), (g) to include decisions by attorney adjudicators, as proposed in section II.B above. We are also proposing to retitle the sections to reflect that the provisions of the section extend to decisions by both ALJ and attorney adjudicators. We are proposing to change the language in §§ 405.1000(a), (b), (c), and (d); and 423.2000(a) and (b) to state that a hearing may only be conducted by an ALJ. These proposals would provide readers with an accurate overview of how a request for an ALJ hearing would be adjudicated, including the potential that a decision could be issued without conducting a hearing by an ALJ or an attorney adjudicator as proposed in section II.B above, while informing readers that if a hearing is conducted, an ALJ will conduct the hearing.

Current § 405.1000(c) provides that CMS or a contractor may elect to participate in a hearing, and § 423.2000(c) provides that CMS, the IRE or Part D plan sponsor may request to participate in a hearing. As discussed in section III.A.3.f below, we are proposing to revise §§ 405.1010 and 423.2010 so that these entities may elect (for § 405.1010) or request (for § 423.2010) to participate in the proceedings on a request for hearing, including participation before a hearing is scheduled. We are proposing to revise §§ 405.1000(c) and 423.2000(c) so that the sections would reference §§ 405.1010 and 423.2010, respectively, with regard to participating in the proceedings. By referencing §§ 405.1010 and 423.2010, the proposed revisions would direct readers to those sections addressing the full scope of potential participation by CMS or its contractors, or a Part D plan sponsor, on a request for an ALJ hearing, including participating in the proceedings on a request for an ALJ hearing, which as discussed in proposed §§ 405.1010 and 423.2010, may include any proceedings before an oral hearing is scheduled. We are also proposing in § 405.1000(c) to state that CMS or its contractor may join the hearing before an ALJ as a party under § 405.1012, which would direct readers to the appropriate section addressing the full scope of CMS or its contractor acting as a party. (Because CMS, the IRE, and the Part D plan sponsor may not be a party to a hearing under part 423, subpart U, there is no corollary to § 405.1012 in that subpart and therefore a similar revision is not proposed for § 423.2000(c).)

Current §§ 405.1000(d) and 423.2000(d) provide that a decision is based on the hearing record, and current §§ 405.1000(g) and 423.2000(g) reference a hearing record in describing when a decision can be issued based on the record, without a hearing. However, current §§ 405.1042 and 423.2042 identify the record as the administrative record. The references to a hearing record in current paragraphs (d) and (g) may cause confusion when no hearing is conducted. To make the terminology consistent throughout the rules, account for decisions that are issued without a hearing being conducted, and minimize confusion, we are proposing to revise §§ 405.1000(d) and 423.2000(d) so that a decision is based on the administrative record, including, for an ALJ, any hearing record, and §§ 405.1000(g) and 423.2000(g) to provide that a decision is based on the administrative record.

Current § 405.1000(e) and (g) discuss two circumstances in which a decision on a request for hearing can be issued by an ALJ without conducting a hearing, either where the parties waive the hearing or where the record supports a fully favorable finding. Related to current § 405.1000(e), current § 405.1000(f) discusses the ALJ's authority to conduct a hearing even if the parties waive the hearing. As discussed in section III.A.3.r below, we are proposing to revise § 405.1038 to modify the circumstances in which a decision on a request for hearing can be issued without conducting a hearing. As discussed in the proposed revisions to § 405.1038, we would require that waivers be obtained by the parties entitled to a notice of hearing in accordance with § 405.1020(c), or to require that the record supports a fully favorable finding for the appellant and there is no other party or no other party is entitled to a notice of hearing in accordance with § 405.1020(c). Proposed § 405.1000(e), (f), and (g) would be revised for consistency with the § 405.1038 proposals and to accurately summarize when a decision on a request for hearing can be issued without conducting a hearing in accordance with proposed § 405.1038. We are not proposing similar changes in § 423.2000(e), (f), and (g) because we are not proposing changes to when a decision on a request for hearing can be issued without conducting a hearing in § 423.2038.

Current § 405.964(c) requires a QIC to consolidate requests for a reconsideration filed by different parties on the same claim before a reconsideration is made on the first timely filed request. While current § 405.1044 permits an ALJ to consolidate requests for hearing if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing pending before the same ALJ, the provision is discretionary and dependent on the requests being assigned to the same ALJ. To mitigate the potential of requests for hearing on the same claim filed by different parties being separately adjudicated, we are proposing to add § 405.1000(h) to require that when more than one party files a timely request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued. We note that if a decision was issued on the first timely request before an additional request is timely filed or good cause is found to extend the period to file the additional request for hearing, a reopening of the decision may be considered by the deciding adjudicator in accordance with § 405.980. For example, if a request is submitted with new and material evidence that was not available at the time of the decision and may result in a different conclusion, the reopening provisions at § 405.980 would apply. Because only the enrollee is a party in a part 423, subpart U proceeding on a request for an ALJ hearing, no corresponding changes are proposed for § 423.2000.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Hearing before an ALJ and decision by an ALJ or attorney adjudicator general rule" at the beginning of your comment.

b. Right to an ALJ Hearing (§§ 405.1002 and 423.2002)

Current §§ 405.1002 and 423.2002 discuss a right to an ALJ hearing. Current §§ 405.1002(a) and 423.2002(a) provide that a party to a QIC reconsideration or the enrollee who receives an IRE reconsideration, respectively, may "request" a hearing before an ALJ if the party or enrollee files a timely request and meets the amount in controversy requirement. However, a party or enrollee is entitled to a hearing only when those requirements are met. See sections 1860D–4(h) and 1869(b)(1)(A) of the Act. Therefore, we are proposing to revise §§ 405.1002(a) and 423.2002(a) introductory text to state that the party to a QIC reconsideration or the enrollee who receives an IRE reconsideration has a right to a hearing rather than may request a hearing. These proposed changes would align the provisions with the statute and clarify that the party or enrollee has a right to a hearing before an ALJ when the criteria are met.

Current §§ 405.1002(a)(4) and 423.2002(e) provide that the request is considered filed on the date it is received by the entity specified in the QIC's or IRE's reconsideration. There has been confusion when a request is sent to an OMHA office that is not specified in the reconsideration, and this error causes delays in processing the request. We are proposing to revise §§ 405.1002(a)(4) and 423.2002(e) to replace "entity" with "office" to avoid confusion that the request may be filed with OMHA as an entity, and therefore any OMHA office, rather than the specific OMHA office identified in the QIC's or IRE's reconsideration. This would help ensure appellants are aware that a request for hearing must be filed with the office indicated in the notice of reconsideration to avoid delays. For example, when the notice of reconsideration indicates that a request for hearing must be filed with the OMHA central docketing office, an appellant will cause a delay if the request is sent to the QIC or IRE, or an OMHA field office. We also note that as explained in the 2009 Final Rule (74 FR 65319 through 65320), pursuant to current § 405.1014(b)(2), if a request for hearing is timely filed with an entity other than the entity specified in the notice of reconsideration, the request is not treated as untimely or otherwise rejected. This would remain true for requests that are timely filed with an office other than the office specified in the notice of reconsideration, pursuant to proposed § 405.1014(c)(2), which incorporates the requirement from current § 405.1014(b)(2). This would also apply in part 423, subpart U adjudications because the same language appears in current § 423.2014(c)(2) and is incorporated in proposed § 423.2014(d)(2).

Current § 405.1002(b)(1) provides that when a party files a request with the QIC to escalate the appeal, it is escalated to "the ALJ level." We are proposing to revise § 405.1002(b)(1) to replace "to the ALJ level" with "for a hearing before an ALJ" so that when a request for a QIC reconsideration is escalated, it is escalated "for a hearing before an ALJ." This would help ensure that the right to a hearing is clear when an appeal is escalated from the QIC. There is no corresponding provision in part 423, subpart U.

Current § 423.2002(c) provides that the ALJ must document all oral requests for expedited hearings. However, an ALJ is not assigned to an appeal until after the request for hearing is received and processed. Thus, we are proposing to revise § 423.2002(c) to state that "OMHA" must document all oral requests for expedited hearings. There is no corresponding provision in part 405, subpart I.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Right to an ALJ hearing" at the beginning of your comment.

c. Right to a Review of QIC or IRE Notice of Dismissal (§§ 405.1004 and 423.2004)

Current §§ 405.1004 and 423.2004 discuss the right to an ALJ review of a QIC notice of dismissal or IRE notice of dismissal, respectively. As proposed in section II.B above, attorney adjudicators or ALJs would conduct reviews of QIC or IRE dismissals. Accordingly, we are proposing to remove references to an ALJ in the titles of proposed §§ 405.1004 and 423.2004, though ALJs would continue to have the authority to conduct reviews of QIC or IRE dismissals if a request for a review of a QIC or IRE dismissal is assigned to an ALJ. We also propose to insert "or attorney adjudicator" after ALJ in §§ 405.1004(a) introductory language, (b), (c); and 423.2004(a) introductory language, (b), and (c), to provide that an attorney adjudicator could review a QIC or IRE dismissal, as proposed in section II.B above. We also are proposing to replace the reference to "entity" in current §§ 405.1004(a)(4) and 423.2004(a)(4), with "office," for the same reasons discussed above in III.A.3.b, for amending parallel language in §§ 405.1002 and 423.2002.

Current §§ 405.1004(b) and 423.2004(b) provide that if an ALJ determines that the QIC's or IRE's dismissal was in error, he or she vacates the dismissal and remands the case to a QIC or IRE. As discussed in III.A.3.p below, we are proposing to revise the remand provisions and add new §§ 405.1056 and 405.1058, 423.2056, and 423.2058 to govern when remands may be issued, whether and to what extent remands may be reviewed, providing notice of a remand, and the effect of a remand. We are also proposing to revise §§ 405.1004(b) and 423.2004(b) to add references to proposed §§ 405.1056 and 423.2056, respectively, to explain that the remand would be in accordance with proposed §§ 405.1056 and 423.2056, which as discussed in section III.A.3.p below, would address issuing remands and notices thereof, including for remands of QIC or IRE dismissals.

Current §§ 405.1004(c) and 423.2004(c) state that an ALJ's decision regarding a QIC's or IRE's dismissal of a reconsideration request is binding and not subject to further review, and that the dismissal of a request for ALJ review of a QIC's or IRE's dismissal of a reconsideration request is binding and not subject to further review, unless vacated by the Council under § 405.1108(h) or § 423.2108(b), respectively. In our experience, these sections as currently drafted have been a source of confusion for adjudicators and appellants. The two sentences convey different actions that can result from a request for review of a QIC or IRE dismissal—a decision regarding whether the QIC's or IRE's dismissal was correct, or a dismissal of the appellant's request for an ALJ review of the QIC's or IRE's dismissal. We are proposing to separate and further distinguish the two situations to avoid the current confusion that results from two of the three possible outcomes that may result from a request to review a QIC or IRE dismissal (the third being a remand of the dismissal, addressed in paragraph (b) in the respective sections) being in the same paragraph by proposing a separate paragraph for each outcome currently addressed in paragraph (c).

We are proposing to revise §§ 405.1004(c) and 423.2004(c) to include the possible outcome in the first sentence of current §§ 405.1004(c) and 423.2004(c) of a decision affirming the QIC's or IRE's dismissal. We also are proposing to move language in current §§ 405.1004(c) and 423.2004(c) stating that the decision of an ALJ on a request for review of a QIC dismissal is binding and not subject to further review, to proposed §§ 405.1048(b) and 423.2048(b), which as discussed in section III.A.3.v below, would address the effects of decisions on requests to review a QIC or IRE dismissal. In addition, we are proposing in §§ 405.1004(c) and 423.2004(c), respectively, to state that a decision affirming a QIC or IRE dismissal would be issued in accordance with proposed §§ 405.1046(b) and 423.2046(b), which as discussed in section III.A.3.v below, would address issuing decisions on requests for review of a QIC or IRE dismissal and notices thereof.

The 2009 Final Rule (74 FR 65311 through 65312) also explained that if a request for ALJ review of a QIC dismissal was invalid and thus subject to dismissal, the dismissal of the request to review a QIC dismissal was binding and not subject to further review (however, a party could request that the dismissal be vacated by the Council pursuant to § 405.1108(b)). We are proposing to add §§ 405.1004(d) and 423.2004(d) to state that the ALJ or attorney adjudicator may dismiss a request for review of a QIC's or an IRE's dismissal in accordance with proposed §§ 405.1052(b) or 423.2052(b), respectively, which as discussed in section III.A.3.x below, would address dismissals of requests for review of a QIC or IRE dismissal and notices thereof. We also are proposing to move language in current §§ 405.1004(c) and 423.2004(c) stating that the dismissal is binding and not subject to further review unless the dismissal is vacated, to proposed §§ 405.1054(b) and 423.2054(b), which would address the effects of a dismissal of a request for review of a QIC's or an IRE's dismissal and as discussed in section III.A.3.x below, would provide authority for an ALJ or attorney adjudicator to vacate a dismissal and therefore replace the current reference to the Council.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Right to a review of QIC or IRE notice of dismissal" at the beginning of your comment.

d. Amount in Controversy Required for an ALJ Hearing (§§ 405.1006, 405.976(b)(7), 423.1970, 422.600(b), and 478.44(a))

Current § 405.1006 sets forth the requirements for meeting the amount in controversy for an ALJ hearing. The title of current § 405.1006 states that the amount in controversy is required to "request" an ALJ hearing and judicial review. However, as discussed in III.A.3.b above, section 1869(b)(1)(A) of the Act states that a party is entitled to a hearing before the Secretary and judicial review, subject to the amount in controversy and other requirements. To align the title of § 405.1006 with the statutory provision, we are proposing that the amount in controversy is required "for" an ALJ hearing and judicial review rather than "to request" an ALJ hearing and judicial review. Put another way, a party may request an ALJ hearing or judicial review, albeit unsuccessfully, without satisfying the amount in controversy requirement.

Section 1869(b)(1)(E) of the Act establishes the minimum amounts in controversy for a hearing by the Secretary and for judicial review, but does not establish how to calculate the amounts in controversy. Current § 405.1006(d) states that the amount remaining in controversy is calculated based on the actual amount charged to the individual (a beneficiary) for the items or services in question (commonly referred to as billed charges), reduced by any Medicare payments already made or awarded for the items or services, and any deductible and coinsurance amounts applicable to the particular case. In an effort to align the amount in controversy with a better approximation of the amount at issue in an appeal, we are proposing to revise the basis (that is, the starting point before any deductions for any payments already made by Medicare or any coinsurance or deductible that may be collected) used to calculate the amount in controversy. For appeals of claims submitted by providers of services, physicians, and other suppliers that are priced based on a published Medicare fee schedule or published contractor priced amount (as discussed below), rather than using the actual amount charged to the individual as the basis for the amount in controversy, we are proposing to use the Medicare allowable amount for the items and/or services being appealed, subject to the exceptions discussed below. An allowable amount is the maximum amount of the billed charge deemed payable for the item or service. For the purposes of the amount in controversy under § 405.1006, we are proposing at § 405.1006(d)(2)(i)(A) that for items and services with a published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy is the allowable amount, which would be the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service.

For a vast majority of items and services furnished and billed by physicians and other suppliers, allowable amounts are determined based on Medicare fee schedules. Fee schedules are updated and published on an annual basis by CMS through rulemaking, and CMS and its contractors have tools and resources available to inform physicians and other suppliers of allowable amounts based on these fee schedules, including the Physician Fee Schedule Look-up Tool available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup/* and spreadsheets for other fee schedules that can be accessed on the CMS Web site through the fee schedule main page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html.* Allowable amounts for many contractor priced items and services are also included in these tools and resources. Allowable amounts are included on the Medicare remittance advice for paid items and services, but not for items and services that are denied. However, where the allowable amount for an item or service is determined based on a published fee schedule or contractor priced amount, we anticipate that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, would be able to use the existing CMS and contractor tools and resources to determine allowable amounts for denied services when filing a request for hearing, and those amounts could be verified by OMHA in determining whether the claims included in the request meet the amount in controversy requirement. As discussed below, where the appellant is a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, CMS would require the QIC to specify in the notice of reconsideration, for partially or fully unfavorable reconsideration decisions, whether the amount remaining in controversy is estimated to meet or not meet the amount required for an ALJ hearing under proposed § 405.1006(d).

Due to the pricing methodology for many items and services furnished by providers of services, such as hospitals, hospices, home health agencies, and skilled nursing facilities, at the present time an allowable amount is not easily discerned or verified with existing CMS and contractor pricing tools (for example, there is no pricing tool available for hospital outpatient services paid under the outpatient prospective payment system (OPPS)) for pre-payment claim denials (where items or services on the claim are denied, in full or in part, before claim payment has been made). Similarly, items and services furnished by providers or suppliers that are always non-covered, as well as unlisted procedures, may not have published allowable amounts based on a fee schedule or a published contractor-priced amount. Therefore, we are proposing at § 405.1006(d)(2)(i)(B) to continue using the provider's or supplier's billed charges as the basis for calculating the amount in controversy for appeals of claims that are not priced according to a CMS-published fee schedule and do not have a published contractor-priced amount (except as discussed below). We note that the method for calculating the amount in controversy in this scenario would be the same as under current § 405.1006(d), and we believe that all appellants have access to this information through claims billing histories, remittance advices, or the column titled "Amount Provider [or Supplier] Charged" on the Medicare Summary Notice. However, we are soliciting comment on whether existing tools and resources are available that would enable providers, suppliers, and Medicaid State agencies to submit an allowable amount in their request for hearing (as proposed in Section III.A.3.g.i below) for items and services not subject to published fee schedules or published contractor priced amounts, and whether those amounts could also be verified by OMHA. We are also soliciting comment on how such tools and resources could be used in appeals filed by beneficiaries.

Current § 405.1006(d)(1) introductory text uses "the actual amount charged the individual for the items and services in question" as the basis (starting point) for calculating the amount in controversy, before any reductions described in paragraphs (d)(1)(i) and (ii) (for any Medicare payments already made or awarded and any deductible and coinsurance applicable in the particular case) occur. For the reasons discussed above, we are proposing to revise paragraph (d)(1) introductory text to state that in situations other than those described in § 405.1006(d)(3) through (7) (discussed below), the amount in controversy is computed as "the basis for the amount in controversy for the items and services in the disputed claim as defined in paragraph (d)(2)", less applicable reductions described in paragraphs (d)(1)(i) and (ii), and are proposing to revise paragraph (d)(2) to specify the amount that would be used as the basis for the amount in controversy on a situational basis. We are also proposing at § 405.1006(d)(3) through (7) five exceptions to the general calculation methodology specified in proposed paragraphs (d)(1) and (2).

There has also been confusion in calculating the amount in controversy when an appealed reconsideration involves multiple claims. Section 1869 of the Act and part 405, subpart I provide for an appeals process in which each claim decision is appealed and separately adjudicated. However, in some instances, claims are considered together based on an appellant's request. To address confusion with calculating the amount in controversy when reconsiderations involve multiple claims and to help ensure § 405.1006 clearly conveys that the amount in controversy requirement must be met for each appealed claim unless the claim can be aggregated as discussed below, proposed § 405.1006(d)(1) would clarify that the amount in controversy is based on the items or services in the disputed "claim."

We are proposing to maintain the current reduction to the calculation of the amount in controversy in § 405.1006(d)(1)(i), which states that the basis for the amount in controversy is reduced by any Medicare payments already made or awarded for the items or services. In addition, current § 405.1006(d)(1)(ii) provides that the basis for the amount in controversy is further reduced by "[a]ny deductible and coinsurance amounts applicable in the particular case." We are proposing to revise § 405.1006(d)(1)(ii) to read, "Any deductible and/or coinsurance amounts that may be collected for the items or services." We believe revising this provision is appropriate to better align the amount at issue in the appeal and the amount in controversy so that in situations where a provider or supplier is prohibited from collecting applicable coinsurance and/or deductible, or must refund any such amounts already collected, the basis for the amount in controversy is not reduced by that amount (for example, if a provider or supplier is held liable for denied services under the limitation on liability provision in section 1879 of the Act, any amounts collected for the denied service, including coinsurance and/or deductible must be refunded).

As discussed above, we are proposing at § 405.1006(d)(2)(i) that, for situations other than those described in § 405.1006(d)(2)(ii) and (iii), the basis for calculating the amount in controversy under § 405.1006(d)(1) would be the Medicare allowable amount, which is the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service if there is a published Medicare fee schedule or published contractor-priced amount for the items or services in the disputed claim; or if there is no published Medicare fee schedule or contractor-priced amount for the items or services in the disputed claim, the basis for the amount in controversy would be the provider or supplier's billed charges submitted on the claim for the items and services. We believe providers, suppliers, and Medicaid State agencies would be able to utilize existing CMS and CMS contractor tools and resources to determine the allowable amount for items and services with published fee schedule or published contractor-priced amounts, and for items or services without a published fee schedule or published contractor priced amount, the calculation methodology for the amount in controversy would be the same as the calculation methodology specified in current § 405.1006(d). However, there may be instances where a beneficiary would appeal a claim for items and services for which the allowable amount would be the basis for the amount in controversy under proposed § 405.1006(d)(2)(i)(A) (for example, a claim for items or services with a published fee schedule or published contractor-priced amount that does not involve an overpayment and for which the beneficiary has not been determined to be financially responsible). We believe most beneficiaries are not familiar with published fee schedule or contractor-priced amounts and may be unable to determine the amount in controversy in these circumstances with the resources currently available to them. However, as discussed below, we are proposing at § 405.976(b)(7) that the QIC include in the notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration is partially or fully unfavorable to the appellant. For appeals filed by beneficiaries, often the amount at issue is aligned not with the Medicare allowable amount, but rather with the billed charges of the provider or supplier. For example, where a beneficiary is held financially responsible for a denied claim under the limitation on liability provisions in section 1879 of the Act because he or she received an Advance Beneficiary Notice of Noncoverage (ABN), the beneficiary is responsible for the billed charges on the claim. Or, for a claim not submitted on an assignment-related basis that is denied, the beneficiary may be responsible for the billed charges, or the billed charges subject to the limiting charge in section 1848(g) of the Act. Medicare notifies the beneficiary of the amount he or she may be billed for denied services on the Medicare Summary Notice in a column titled, "Maximum You May Be Billed." For appeals filed by a provider, supplier, or Medicaid State agency for denied items or services for which the beneficiary was determined to be financially responsible, we believe providers, suppliers, and Medicaid State agencies would have sufficient access to the provider or supplier's billing information and Medicare claims processing data to determine the amount charged to the beneficiary. Accordingly, we are proposing at § 405.1006(d)(2)(ii) that for any items or services for which a beneficiary has been determined to be financially responsible, the basis for the amount in controversy is the actual amount charged to the beneficiary (or the maximum amount the beneficiary may be charged if no bill has been received) for the items or services in the disputed claim. As discussed above, this amount would be set forth on the Medicare Summary Notice in the column titled "Maximum You May Be Billed."

We are also proposing at § 405.1006(d)(2)(iii) that if a beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authorities, the basis for the amount in controversy would be the actual amount originally charged to the beneficiary for the items or services in the disputed claim, as we believe that the amount originally charged to the beneficiary is more reflective of the actual amount at issue for the beneficiary and for the provider or supplier in this situation. We believe appellants would have access to and would use the same information for determining the basis for the amount in controversy under paragraph § 405.1006(d)(2)(iii) as they would under § 405.1006(d)(2)(ii).

As discussed above, we are proposing at § 405.1006(d)(3) through (7) five exceptions to the general methodology used to calculate the amount in controversy specified in § 405.1006(d)(1). Current § 405.1006(d)(2) provides that, notwithstanding current § 405.1006(d)(1), when payment is made for items or services under section 1879 of the Act or § 411.400, or the liability of the beneficiary for those services is limited under § 411.402, the amount in controversy is computed as the amount that the beneficiary would have been charged for the items or services in question if those expenses were not paid under § 411.400 or if that liability was not limited under § 411.402, reduced by any deductible and coinsurance amounts applicable in the particular case. We are proposing to re-designate current § 405.1006(d)(2) as § 405.1006(d)(3) and to revise the paragraph to state that when payment is made for items or services under section 1879 of the Act or § 411.400, or the liability of the beneficiary for those services is limited under § 411.402, the amount in controversy would be calculated in accordance with § 405.1006(d)(1) and (2)(i), except there is no deduction under paragraph (d)(1)(i) for expenses that are paid under § 411.400 or as a result of liability that is limited under § 411.402. For example, when a claim for items or service is denied under section 1862(a)(1)(A) of the Act because the items or services were not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member, Medicare payment may nonetheless be made under the limitation on liability provisions of § 1879 of the Act if neither the provider/supplier nor the beneficiary knew, or could reasonably have been expected to know, that payment would not be made. In instances such as these, we are proposing that the amount in controversy would be calculated as if the items or services in the disputed claim were denied and no payment had been made under section 1879 of the Act. We believe this exception is appropriate because appellants may still wish to appeal findings of non-coverage related to items and services for which liability of the party was limited or payment was made under section 1879 of the Act or § 411.400 or for which the beneficiary was indemnified under § 411.402, but if these payments or indemnifications were deducted from the basis for the amount in controversy, the amount in controversy could be zero. As this exception relates only to whether deductions are made under § 405.1006(d)(1)(i) for any Medicare payments already made or awarded for the items or service, and the amount in controversy would otherwise be calculated in accordance with proposed § 405.1006(d)(1) and (d)(2)(i), we believe appellants would have access to and would use the same information for determining the amount in controversy under § 405.1006(d)(3) as they would under § 405.1006(d)(1) and (d)(2)(i).

Current § 405.1006 does not address calculating the amount in controversy for matters involving a provider or supplier termination of a Medicare-covered item or service when the beneficiary did not elect to continue receiving the item or service (for example, § 405.1206(g)(2) provides that if a beneficiary is dissatisfied with a QIO's determination on his or her discharge and is no longer an inpatient in a hospital, the determination is subject to the general claims appeal process). In this circumstance, items and services have not been furnished, and therefore, a claim has not been submitted. Yet the beneficiary may elect not to continue receiving items or services while appealing the provider or supplier termination due to potential financial responsibility for the items or services. While an amount in controversy cannot be assessed for a period of time during which no items or services were furnished, a beneficiary may assert a continuing need for the items or services based on his or her condition at the time an appeal is heard. To address this circumstance, we are proposing new § 405.1006(d)(4), which would provide that when a matter involves a provider or supplier termination of Medicare-covered items or services and the beneficiary did not elect to continue receiving the items or services that are disputed by a beneficiary, the amount in controversy is calculated as discussed above regarding proposed (d)(1) and (d)(2)(ii) (which addresses situations where the beneficiary is determined to be financially responsible), except that the basis for the amount in controversy and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services that the beneficiary asserts should be covered by Medicare based on the beneficiary's current condition at the time an appeal is heard, and Medicare payment was not made. This proposal would allow the beneficiary to pursue coverage for an item or service and potentially meet the amount in controversy requirement in instances in which he or she would not otherwise be able to pursue a hearing before an ALJ because no items or services have been rendered and therefore no amount in controversy exists because there is no disputed claim. In these instances, the beneficiary has been notified of a preliminary decision by a provider or supplier that Medicare will not cover continued provision of the items or services in dispute. Therefore, we believe using the amount the beneficiary would be charged if the beneficiary elected to continue receiving the items or services that the beneficiary asserts should be covered and if Medicare payment were not made for these items or services (in other words, the amount the beneficiary would be charged if the beneficiary were financially responsible for these items or services) is most reflective of the actual amount in dispute. Most beneficiary appeals of provider or supplier terminations of Medicare-covered items or services involve the termination of Part A services and, therefore, we expect it would be rare that the amount in controversy would be less than that required for an ALJ hearing. However, we expect that beneficiaries wishing to determine if the amount in controversy required for an ALJ hearing was met could obtain from the provider or supplier the amount the beneficiary would be charged if the beneficiary elected to continue receiving the items or services and Medicare payment were not made. In addition, as discussed below, we are proposing at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

We considered using Medicare payable amounts for denied items and services as the basis for the amount in controversy calculation specified in proposed § 405.1006(d)(1), as that would be a more precise estimate of the amount at issue in the appeal than either the Medicare allowable amount or the billed charges. Payable amounts would take into account payment rules related to the items and services furnished that may increase or decrease allowable amounts (for example, multiple surgery reductions, incentive payments, and competitive bidding payments). However, CMS systems do not currently calculate payable amounts for denied services, and undertaking major system changes would delay implementation and has been determined not to be cost effective. While payable amounts may be a better representation of the amount at issue in the appeal, we believe the Medicare allowable amount and the other amount in controversy calculations provided in proposed § 405.1006(d) are appropriate and reliable estimates that align well with the amount at issue for claims for which a payable amount has not been calculated.

However, for post-payment denials, or overpayments, a payable amount has been determined and would be the most reliable indicator of the amount actually at issue in the appeal. Therefore, we are proposing new § 405.1006(d)(5) to state that, notwithstanding the calculation methodology in proposed paragraphs (d)(1) and (2), when a claim appeal involves an overpayment determination, the amount in controversy would be the amount of the overpayment specified in the demand letter. In a post-payment denial, the amount of the overpayment identified in the demand letter is readily available to appellants, and is the most accurate reflection of the amount actually at issue in the appeal. In addition, current § 405.1006 does not address appeals that involve an estimated overpayment amount determined through the use of sampling and extrapolation. In this circumstance, the claims sampled to determine the estimated overpayment may not individually meet the amount in controversy requirement, but the estimated overpayment determined through the use of extrapolation may meet the amount in controversy requirement. To address this circumstance, we are also proposing in new § 405.1006(d)(5) that when a matter involves an estimated overpayment amount determined through the use of sampling and extrapolation, the estimated overpayment as extrapolated to the entire statistical sampling universe is the amount in controversy. This proposal would provide appellants the opportunity to appeal claims that may not individually meet the amount in controversy requirement if such claims were part of the sample used in making an overpayment determination that does meet the amount in controversy requirement. Because the overpayment determination reflects the amount for which the appellant is financially responsible, we believe it would be appropriate to allow appellants to appeal individual claims in the sample that was used to determine the overpayment. Whether an appeal involves an individual overpayment or an estimated overpayment determined through the use of sampling and extrapolation, we believe appellants against whom an overpayment was assessed would need only to consult the demand letter they received in order to determine the amount in controversy. However, we expect there may be circumstances where a beneficiary wishes to appeal an overpayment that was assessed against a provider or supplier, and in these situations the beneficiary may not have a copy of the demand letter that was received by the provider or supplier. For this reason, and as discussed below, we are proposing at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable. We are also proposing new § 405.1006(d)(6), which would provide that when a beneficiary files an appeal challenging only the computation of a coinsurance amount, or the amount of a remaining deductible applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct. We believe this provision is appropriate in these instances because, without this provision, the amount in controversy determined under the general calculation methodology in § 405.1006(d)(1) would be zero for a paid claim. In addition, we believe that the calculation proposed at § 405.1006(d)(6) would appropriately reflect the amount at issue for the beneficiary in these appeals where the computation of a coinsurance amount, or the amount of a remaining applicable deductible is challenged. We believe beneficiaries would have access to the coinsurance and/or deductible amounts determined by the contractor for the paid claim on the beneficiary's Medicare Summary Notice, in the column titled "Maximum You May Be Billed," and would need only to subtract the amount of coinsurance and/or deductible the beneficiary believes he or she should have been charged in order to arrive at the amount in controversy. We expect it would be extremely rare for a non-beneficiary appellant to file an appeal challenging the computation of a coinsurance amount or the amount of a remaining deductible.

In addition, we are proposing new § 405.1006(d)(7), which would provide that for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected in the published Medicare fee schedule or in the published contractor priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services. We believe this provision is appropriate in these instances because, without this provision, the amount in controversy determined under the general calculation methodology in § 405.1006(d)(1) would be zero for such paid claims. In addition, we believe that the calculation proposed at § 405.1006(d)(7) would appropriately reflect the amount at issue for the appellant in these appeals. We believe that, generally, these types of appeals are filed by providers and suppliers who are already familiar with the allowable amount for the items or services in the disputed claim based on information obtained from published fee schedules or contractor-priced amounts. Further, we believe that a fee schedule or contractor price challenge filed by a beneficiary on a paid claim would be a very rare occurrence. However, as discussed below, in the event a beneficiary would want to file such an appeal, the beneficiary could obtain an estimate of the amount in controversy from the QIC reconsideration. As discussed further below, we are proposing at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

In the event that a reconsideration, or a redetermination if the appeal was escalated from the QIC without a reconsideration, involves multiple claims and some or all do not meet the amount in controversy requirement, section 1869 of the Act states that, in determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve the delivery of similar or related services to the same individual by one or more providers or suppliers, or common issues of law and fact arising from services furnished to two or more individuals by one or more providers or suppliers. Under this authority, § 405.1006(e) provides for aggregating claims to meet the amount in controversy requirement.

The title of current § 405.1006(e)(1) for aggregating claims when appealing a QIC reconsideration is phrased differently than the corresponding title for aggregating claims when escalating a request for a QIC reconsideration in current § 405.1006(e)(2), which may cause confusion. We are proposing to revise the title to § 405.1006(e)(1) to "Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing" so it clearly applies to aggregating claims in appeals of QIC reconsiderations, and is parallel to the phrasing used in the title of § 405.1006(e)(2). The proposed titles of § 405.1006(e)(1) and (e)(2), and proposed § 405.1006(e)(2)(ii) would also replace "to the ALJ level" with "for an ALJ hearing" to again highlight that the appeal of a QIC reconsideration or escalation of a request for a QIC reconsideration is for an ALJ hearing.

Current § 405.1006(e)(1)(ii) provides that to aggregate claims, the request for ALJ hearing must list all of the claims to be aggregated. This has caused confusion because some appellants read current § 405.1006(e)(1)(ii) as allowing appeals of new claims to be aggregated with claims in previously filed appeals, provided the new request for hearing lists the claims involved in the previously filed appeals. However, current § 405.1006(e)(2)(i), which applies to aggregating claims that are escalated from the QIC for a hearing before an ALJ, requires that the claims were pending before the QIC in conjunction with the same request for reconsideration. We note that in the context of a request for hearing, aggregating new claims with claims from previously filed requests could delay the adjudication of the requests and is inconsistent with the current rule for aggregating claims that are escalated from the QIC. To address these issues and bring consistency to the aggregation provisions, we are proposing to revise § 405.1006(e)(1)(ii) to require the appellant(s) to request aggregation of the claims in the same request for ALJ hearing or in multiple requests for an ALJ hearing filed with the same request for aggregation. This would allow an individual or multiple appellants to file either one request for an ALJ hearing for multiple claims to be aggregated, or multiple requests for an ALJ hearing for the appealed claims when requesting aggregation, while requiring them to be filed together with the associated request for aggregation. We are also proposing in § 405.1006(e)(1)(iii) and (e)(2)(iii) that an ALJ or attorney adjudicator may determine that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, but only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. We are proposing this because an attorney adjudicator adjudicating requests for an ALJ hearing when no hearing is conducted, as proposed in section II.B above, would not be permitted under this proposed rule to dismiss a request for an ALJ hearing due to procedural issues such as an invalid aggregation request. Because only an ALJ would be permitted to dismiss a request for an ALJ hearing because there is no right to a hearing, which includes not meeting the amount in controversy requirement for a hearing, in accordance with proposed § 405.1052(a), an attorney adjudicator could not make a determination that the aggregation criteria were not met because that determination would result in a dismissal of a request for an ALJ hearing.

Current § 405.976(b)(7) requires that the QIC notice of reconsideration contain a statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable. We are proposing to revise § 405.976(b)(7) to require that the QIC notice of reconsideration include a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing only if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration is partially or fully unfavorable. In line with current practice, we are not proposing to require that the QIC indicate what it believes to be the exact amount in controversy, but rather only an estimate of whether it believes the amount in controversy is met, because we believe the ultimate responsibility for determining whether the amount in controversy required for an ALJ hearing is met lies with appellants, subject to verification by an ALJ or attorney adjudicator (though, as discussed in section II.B above, only an ALJ would be able to dismiss a request for hearing for failure to meet the amount in controversy required for an ALJ hearing). We believe that providers, suppliers, and Medicaid State agencies have the tools, resources, and payment information necessary to calculate the amount in controversy in accordance with § 405.1006(d), and are familiar with the allowable amounts for the places of service in which they operate. Furthermore, applicable plans against whom a Medicare Secondary Payer overpayment is assessed would have access to the overpayment amount specified in the demand letter, which would be used to determine the amount in controversy under proposed § 405.1006(d)(5). Thus, we do not believe it is necessary for the QICs to continue to provide this statement for providers, suppliers, applicable plans, Medicaid State agencies, or beneficiaries represented by providers, suppliers or Medicaid State agencies. Furthermore, as discussed in section III.A.3.g.i below, we are proposing that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, include the amount in controversy in their requests for hearing (unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services). As providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency would be responsible for calculating the amount in controversy and including it on the request for hearing as proposed in section III.A.3.g.i, we do not believe a statement by the QIC that indicates only whether the amount in controversy was or was not met adds significant value to such appellants. Furthermore, we expect that the Medicare allowable amount under proposed § 405.1006(d)(2)(i)(A) would be the basis for the amount in controversy in the majority of Part B appeals filed by non-beneficiary appellants. While QICs have access to the amount charged to an individual based on billed charges, the allowable amounts for claims vary based on where these items and services were furnished, and the applicable fee schedules and contractor-priced amounts, and continuing to require the QICs to include a statement whether the amount in controversy needed for an ALJ hearing is met in all instances in which the decision is partially or fully unfavorable to the appellant would require substantially more work by the QIC, and could delay reconsiderations and increase costs to the government.

Although we are not proposing that beneficiaries who are not represented by a provider, supplier, or Medicaid State agency would need to include the amount in controversy on their requests for hearing (as discussed later in this preamble), we do believe there may be instances where a beneficiary would want to know if the amount in controversy meets the amount required for an ALJ hearing when deciding whether to file a request for hearing. We believe there may be instances where a beneficiary who is not represented by a provider, supplier, or Medicaid State agency may not currently have sufficient information to determine whether the amount in controversy required for an ALJ hearing is met under proposed § 405.1006. For example, under proposed § 405.1006(d)(2)(i)(A), for items and services with a published Medicare fee schedule or published contractor-priced amount (and for which the beneficiary was determined to be not financially responsible), the basis for the amount in controversy would generally be the allowable amount, which is the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service. Beneficiaries not represented by a provider, supplier, or Medicaid State agency would not generally be expected to be familiar with fee schedule and contractor-priced amounts, and we believe they may have difficulty determining whether the amount in controversy required for an ALJ hearing is met in these cases. We also believe beneficiaries not represented by a provider, supplier, or Medicaid State agency might be unable to determine the amount of an overpayment assessed against a provider or supplier for items or services furnished to the beneficiary for purposes of calculating the amount in controversy under proposed § 405.1006(d)(5), as the beneficiary might not have access to the demand letter received by the provider or supplier, and may no longer have access to the Medicare Summary Notice reflecting the original payment amount. Accordingly, because there are situations where such beneficiaries may not have sufficient information to determine the amount in controversy, we are proposing to revise § 405.976(b)(7) to state that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

Current § 423.1970 describes the amount in controversy requirement for part 423, subpart U proceedings. For the same reasons we are proposing to revise § 405.1006(e)(1)(ii), we are proposing in § 423.1970(c)(1)(ii) and (c)(2)(ii) to provide that a single enrollee's or multiple enrollees' request for aggregation, respectively, must be filed at the same time the request (or requests) for hearing for the appealed reconsiderations is filed. In addition, we are proposing to revise § 423.1970(c)(1)(ii) and § 423.1970(c)(2)(ii) to state that the request for aggregation and requests for hearing must be filed within 60 calendar days after receipt of the notice of reconsideration for each reconsideration being appealed, unless the deadline is extended in accordance with § 423.2014(d). This will help ensure there is no confusion that the timely filing requirement applies to each of the requests for hearing filed with the request for aggregation. Because we are proposing to directly reference the 60 calendar day filing requirement under

§ 423.1972(b) and the possible extension of the filing requirement under § 423.2014(d), we are also proposing to remove the current references in § 423.1970(c)(1)(ii) and (c)(2)(ii) to the filing requirement in § 423.1972(b). In addition, for the same reasons we are proposing to revise § 405.1006(e)(1)(iii) and (e)(2)(iii), we are proposing in § 423.1970(c)(1)(iii) and (c)(2)(iii) that an ALJ or attorney adjudicator may determine that the appeals that a single enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, or the appeals that multiple enrollees seek to aggregate involve the same prescription drugs, but only an ALJ may determine appeals that a single enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee, or the appeals that multiple enrollees seek to aggregate do not involve the same prescription drugs. We are proposing to replace "prescription" in current § 423.1970(c)(2)(iii) with "prescription drugs" in proposed § 423.1970(c)(2)(iii) for consistency with current and proposed § 423.1970(c)(1)(iii). Finally, we are also proposing to correct the spelling of "prescription" in current § 423.1970(c)(2)(iii).

Current § 422.600(b) provides that the amount in controversy for appeals of reconsidered determinations to an ALJ (under the Part C Medicare Advantage program), is computed in accordance with part 405. However, if the basis for the appeal is the MAO's refusal to provide services, current § 422.600(c) provides that the projected value of those services are used to compute the amount in controversy. We are not proposing to revise these provisions because we believe the proposed revisions to § 405.1006 described above encompass and have application to the scenarios appealed under part 422, subpart M. In particular, we note that as is the case under current § 405.1006, if an enrollee received items or services and is financially responsible for payment because the MAO has refused to cover the item or services, the amount in controversy would be calculated using the billed charges as the basis for the amount in controversy, as provided in proposed § 405.1006(d)(2)(ii). If the enrollee did not receive the items or services, the provisions of current § 422.600(c) would apply. We also note that current §§ 422.622(g)(2) and 422.626(g)(3) provides for an appeal to an ALJ, the Council, or federal court of an IRE's affirmation of a termination of provider services "as provided for under [part 422, subpart M]," thus triggering the amount in controversy rules in 422.600, which cross-reference part 405 (that is, the rules proposed here). Proposed § 405.1006 would address scenarios appealed under part 422, subpart M that are not clearly addressed in current § 405.1006, such as provider service terminations, which would be addressed in proposed § 405.1006(d)(4), and coinsurance and deductible challenges, which would be addressed in proposed § 405.1006(d)(6).

Current § 478.44(a) also references back to part 405 provisions for determining the amount in controversy when requesting an ALJ hearing after a QIO reconsidered determination. We have proposed revisions to § 478.44 in section III.D.3, below, to update part 405 references, but we are not proposing in § 478.44 to revise how the current or proposed part 405 provision would be applied in calculating the amount in controversy. Similar to the part 422, subpart M provisions discussed above, we believe the proposed revisions to § 405.1006 described above encompass and have application to the scenarios appealed under part 478, subpart B.

We are inviting public comments on these proposals. If you choose to comment on issues in this section, please include the caption "Amount in controversy required for an ALJ hearing" at the beginning of your comment.

e. Parties to an ALJ Hearing (§§ 405.1008 and 423.2008)

Current §§ 405.1008 and 423.2008 discuss the parties to an ALJ hearing. Because current §§ 405.1002(a) and 423.2002(a) already address who may request a hearing before an ALJ after a QIC or IRE issues a reconsideration and current § 405.1002(b) addresses who may request escalation of a request for a QIC reconsideration, we are proposing to remove current §§ 405.1008(a) and 423.2008(a).

We are proposing to retain and revise the language as discussed below in current §§ 405.1008(b) and 423.2008(b), but remove the paragraph designation. Current §§ 405.1008(b) and 423.2008(b) identify the parties "to the ALJ hearing," but this could be read to be limited to parties to an oral hearing, if a hearing is conducted. To address this potential confusion, we are proposing to revise §§ 405.1008 and 423.2008 to replace "parties to an ALJ hearing" with "parties to the proceedings on a request for an ALJ hearing" and "party to the ALJ hearing" with "party to the proceedings on a request for an ALJ hearing." Likewise, we also are proposing to revise the titles to §§ 405.1008 and 423.2008 from "Parties to an ALJ hearing" to "Parties to the proceedings on a request for an ALJ hearing."

We are inviting public comments on these proposals. If you choose to comment the proposals in this section, please include the caption "Parties to an ALJ hearing" at the beginning of your comment.

f. CMS and CMS Contractors as Participants or Parties in the Adjudication Process (§§ 405.1010, 405.1012, and 423.2010)

Consistent with section 1869(c)(3)(J) of the Act, §§ 405.1010 and 405.1012 allow CMS and its contractors to elect to be a participant or a party to a Part A or Part B hearing before an ALJ. Current § 423.1010 allows CMS, a Part D plan sponsor, or an IRE to request to be a participant in the proceedings of a Part D hearing before an ALJ. Since current §§ 405.1010, 405.1012, and 423.2010 were added, CMS and its contractors, including the Part D IRE, and Part D plan sponsors, have assisted the ALJ hearing process by clarifying factual and policy issues, which provides ALJs with more information to resolve the issues on appeals. However, as we have gained experience with CMS and these entities as participants and parties to hearings, we have heard from ALJs and stakeholders that additional parameters are needed to help ensure hearings with the entities are as efficient as possible; expectations and roles are clear; and the entities have an opportunity to assist with appeals for which no hearing is conducted.

Therefore, we are proposing significant revisions to §§ 405.1010, 405.1012, and 423.2010 to achieve these objectives.

Proposed §§ 405.1010 (When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing), 405.1012 (When CMS or its contractors may be a party to a hearing), and 423.2010 (When CMS, the IRE, or Part D plan sponsor may participate in the proceedings on a request for an ALJ hearing) would be reorganized and aligned for clarity, and revised to improve the participation process. The proposed revised sections would be similarly structured to address when an entity may elect or request to participate in the proceedings on a request for an ALJ hearing, or be a party to a hearing; how elections or requests are made; the roles and responsibilities of CMS and its contractors; limitations on hearing participation; and invalid elections or requests.

i. Section 405.1010: When CMS or Its Contractors May Participate in the Proceedings on a Request for an ALJ Hearing

Current § 405.1010(a) provides that an ALJ may request, but may not require, CMS and/or its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any, and CMS or its contractors may elect to participate in the hearing process. Under current § 405.1010(b), if that election is made, CMS or its contractor must advise the ALJ, the appellant, and all other parties identified in the notice of hearing of its intent to participate no later than 10 calendar days after receiving the notice of hearing. Section 405.1010(c) sets forth what participation includes and § 405.1010(d) states that participation does not include CMS or its contractor being called as a witness during the hearing. Section 405.1010(e) requires CMS or its contractors to submit any position papers within the time frame designated by the ALJ. Finally, § 405.1010(f) states that the ALJ cannot draw any adverse inferences if CMS or a contractor decides not to participate in any proceedings before an ALJ, including the hearing.

The reference to the period in which an election to participate must be filed beginning upon receipt of the notice of hearing in current § 405.1010(b) has caused confusion when CMS or its contractors attempt to enter proceedings before a hearing is scheduled, or when no notice of hearing is necessary because an appeal may be decided on the record. To help ensure that CMS and its contractors have the opportunity to enter the proceedings with minimal disruption to the adjudication process prior to a hearing being scheduled or when a hearing may not be conducted, we are proposing in § 405.1010(a)(1) to provide that CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b), at either of, but not later than, two distinct points in the adjudication process described in paragraph (b)(3).

As provided in current § 405.1010(a) and (f), we are proposing at § 405.1010(a)(2) that an ALJ may request but may not require CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any; and the ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in the proceedings.

We are proposing in § 405.1010(b) to address how CMS or a contractor makes an election to participate in an appeal, before or after receipt of a notice of hearing or when a notice of hearing is not required. Under proposed § 405.1010(b)(1), we are proposing that if CMS or a contractor elects to participate before receipt of a notice of hearing (such as during the 30 calendar day period after being notified that a request for hearing was filed as proposed in § 405.1010(b)(3)(i)) or when a notice of hearing is not required, CMS or the contractor must send written notice of its intent to participate to the parties who were sent a copy of the notice of reconsideration, and to the assigned ALJ or attorney adjudicator, as proposed in section II.B above, or if the appeal is not yet assigned, to a designee of the Chief ALJ. Proposed § 405.1010(b)(1) would provide for sending the written notice of intent to participate to an ALJ or attorney adjudicator assigned to an appeal because, as we discuss in proposed in section II.B, an attorney adjudicator also would have the authority to issue decisions on a request for an ALJ hearing when no hearing is conducted, and in accordance with proposed § 405.1010, CMS or its contractors are permitted to participate in the proceedings on such a request. Proposed § 405.1010(b)(1) would also provide for sending the notice of intent to participate to a designee of the Chief ALJ if a request for an ALJ hearing is not yet assigned to an ALJ or attorney adjudicator because CMS or a contractor could file an election to be a participant in the proceedings before the assignment process is complete. Proposed § 405.1010(b)(1) would help ensure that the potential parties to a hearing, if a hearing is conducted, would receive notice of the intent to participate, and also help ensure that adjudicators who are assigned to an appeal after an election is made would be aware of the election. Because only an ALJ may conduct a hearing and the parties to whom a notice of hearing is sent may differ from the parties who were sent a copy on the notice of reconsideration, we are proposing at § 405.1010(b)(2) that if CMS or a contractor elects to participate after receiving a notice of hearing, CMS or the contractor would send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

Under proposed § 405.1010(b)(3)(i), CMS or a contractor would have an initial opportunity to elect to be a participant in an appeal within 30 calendar days after notification that a request for hearing has been filed with OMHA, if no hearing is scheduled. CMS and its contractors have the capability to see that a QIC reconsideration had been appealed to OMHA in the case management system used by QICs. This system would provide constructive notice to the QICs when the system indicates an appeal has been filed with OMHA, which OMHA can monitor through the date that the reconsideration data is transferred to OMHA to adjudicate the request for an ALJ hearing. Under proposed § 405.1010(b)(3)(ii), a second opportunity to elect to be a participant in an appeal would become available if a hearing is scheduled; as in the current rule, CMS or a contractor would have 10 calendar days after receiving the notice of hearing to make the election.

We considered allowing CMS or a contractor to make an election at any time prior to a decision being issued if a hearing was not scheduled, or sending a notice that a decision would be issued without a hearing and establishing an election period after such notice. However, both of these options would disrupt and delay the adjudication process, as well as add administrative burdens on OMHA. We believe the 30 calendar day period after notification that a request for hearing was filed is sufficient time for CMS or a contractor to determine whether to elect to be a participant in the appeal while the record is reviewed for case development and to prepare for the hearing, or determine whether a decision may be appropriate based on the record in accordance with § 405.1038.

We are proposing to consolidate current § 405.1010(c) through (e) in proposed § 405.1010(c) to address the roles and responsibilities of CMS or a contractor as a participant. Proposed § 405.1010(c)(1) would incorporate current § 405.1010(c), which provides that participation may include filing position papers or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, we are proposing to revise § 405.1010(c) to state in § 405.1010(c)(1) that participation may include filing position papers "and/or" providing testimony to emphasize that either or both may be done, and to state that participation would be subject to proposed § 405.1010(d)(1) through (3) (discussed below). We are proposing to incorporate current § 405.1010(d) in proposed § 405.1010(c)(2) to provide that when CMS or a contractor participates in a hearing, they may not be called as witnesses and, thus, are not subject to examination or cross-examination by parties to the hearing. However, to be clear about how a party and the ALJ may address statements made by CMS or a contractor during the hearing given that limitation, we also are proposing in § 405.1010(c)(2) that the parties may provide testimony to rebut factual or policy statements made by the participant, and the ALJ may question the participant about the testimony.

We are proposing to incorporate current § 405.1010(e) in proposed § 405.1010(c)(3) with certain revisions as discussed below. Current § 405.1010(e) states that CMS or its contractor must submit any position papers within the time frame designated by the ALJ. We are proposing in § 405.1010(c)(3) to include written testimony in the provision, establish deadlines for submission of position papers and written testimony that reflect the changes in participation elections in proposed 405.1010(b), and require that copies of position papers and written testimony be sent to the parties. Specifically, we are proposing in § 405.1010(c)(3)(i) that CMS or a contractor position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the scheduled hearing unless additional time is granted by the ALJ. We are proposing to add ''written testimony'' to recognize that CMS or a contractor may submit written testimony as a participant, in addition to providing oral testimony at a hearing. We are proposing to require position papers and written testimony be submitted within 14 calendar days after an election if no hearing is scheduled to help ensure the position paper and/or written testimony are available when determinations are made to schedule a hearing or issue a decision based on the record in accordance with § 405.1038. We also are proposing to require that if a hearing is scheduled, position papers and written testimony be submitted no later than 5 calendar days prior to the hearing (unless the ALJ grants additional time) to help ensure the ALJ and the parties have an opportunity to review the materials prior to the hearing. Additionally, under proposed § 405.1010(c)(3)(ii), CMS or a contractor would need to send a copy of any position paper or written testimony submitted to OMHA to the parties who were sent a copy of the notice of reconsideration if the position paper or written testimony is submitted to OMHA before receipt of a notice of hearing, or to the parties who were sent a copy of the notice of hearing if the position paper or written testimony is submitted after receipt of a notice of hearing. Current § 405.1010 does not address the repercussions of a position paper not being submitted in accordance with the section. Therefore, we are proposing in § 405.1010(c)(3)(iii) that a position paper or written testimony would not be considered in deciding an appeal if CMS or a contractor fails to send a copy of its position paper or written testimony to the parties, or fails to submit its position paper or written testimony within the established time frames. This would help ensure CMS or contractor position papers and written testimony are submitted timely and shared with the parties.

Current §§ 405.1010 does not limit the number of entities that may elect to be participants, which currently includes participating in a hearing if a hearing is conducted, and current § 405.1012 does not limit the number of entities that may elect to be a party to a hearing. This has resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections. To address these issues, we are proposing at § 405.1010(d)(1) that when CMS or a contractor has been made a party to the hearing under § 405.1012, CMS or a contractor that elected to be a participant under § 405.1010 may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case (oral testimony and attendance at the hearing would not be permitted). Similarly, we are proposing at § 405.1010(d)(1) that CMS or a contractor that elected to be a party to the hearing, but was made a participant under § 405.1012(d)(1), as discussed below, would also be precluded from participating in the oral hearing, but would be permitted to file a position paper and/or oral testimony to clarify factual or policy issues in the case. We are proposing at § 405.1010(d)(2) that if CMS or a contractor did not elect to be a party to the hearing under § 405.1012, but more than one entity elected to be a participant under § 405.1010, only the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the oral hearing, but additional entities that filed a subsequent response to the notice of hearing could file a position paper and/or written testimony to clarify factual or policy issues in the case (though they would not be permitted to attend the hearing or provide oral testimony). We are proposing that the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the hearing for administrative efficiency. Under this approach, if multiple entities elected to participate in the proceedings prior to the issuance of a notice of hearing, in accordance with proposed § 405.1010(b)(1), any of these entities wishing to participate in the oral hearing would need to indicate this intention in the response to the notice of hearing. If more than one entity indicated its intention to attend and participate in the oral hearing, only the first entity to file its response would be permitted to do so. The remaining entities would be permitted only to file a position paper and/or written testimony (unless the ALJ grants leave to additional entities to attend the hearing, as discussed below). We considered an alternate proposal of the first entity that made an election to participate being given priority for participating in the hearing, but believe that would result in other participants being uncertain whether they will be participating in the hearing until as few as 5 days prior to the hearing. We also considered a process in which the ALJ would assess which participant that responded to the notice of hearing would be most helpful to the ALJ at the hearing, or in the alternative, permitting all participants to be at the hearing unless the ALJ determined a participant is not necessary for the hearing, but both of these approaches would add administrative burden to the ALJ and could result in participants and parties being uncertain of which participants will be at the hearing until shortly before the hearing. We welcome comments on the alternatives considered above, and other potential alternatives.

Notwithstanding the limitations on CMS and CMS contractor participation in proposed § 405.1010(d)(1) and (2), proposed § 405.1010(d)(3) would provide the ALJ with the necessary discretion to allow additional participation in the oral hearing when the ALJ determines an entity's participation is necessary for a full examination of the matters at issue. For example, if an appeal involves LCDs from multiple MAC jurisdictions, the ALJ may determine that allowing additional MACs to participate in a hearing is necessary for a full examination of the matters at issue. Similarly, if an overpayment determined through the use of a statistical sample and extrapolation is at issue, the ALJ may determine that allowing the contractor that conducted the sampling to participate in the hearing is necessary to address issues related to the sampling and extrapolation, in addition to another contractor that made an election to clarify the policy and factual issues related to the merits of claims in the sample.

Currently, there are no provisions in § 405.1010 to address the possibility of CMS or a contractor making an invalid election. We are proposing to revise § 405.1010(e) to add new provisions to establish criteria for when an election may be deemed invalid and provide standards for notifying the entity and the parties when an election is deemed invalid. Proposed § 405.1010(e)(1) would provide that an ALJ or attorney adjudicator may determine an election is invalid if the election was not timely filed or the election was not sent to the correct parties. This would help ensure that CMS and its contractors make timely elections and inform parties of elections. To provide notice to the entity and the parties that an election was deemed invalid, proposed § 405.1010(e)(2) would require a written notice of an invalid election be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election. If no hearing is scheduled for the appeal or the election was submitted after the hearing occurred, proposed § 405.1010(e)(2)(i) would provide that the notice of an invalid election be sent no later than the date the decision, dismissal, or remand notice is mailed. If a hearing is scheduled for the appeal, proposed § 405.1010(e)(2)(ii) would provide that the written notice of an invalid election is sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Section 405.1010: When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing" at the beginning of your comment.

ii. Section 423.2010: When CMS, the IRE, or Part D Plan Sponsors May Participate in the Proceedings on a Request for an ALJ Hearing

Current § 423.2010 is similar to current § 405.1010, except that CMS, the IRE, or the Part D plan sponsor may only request to participate, and the time periods to request to participate are shorter than the time periods to elect to participate under § 405.1010, which provides the ALJ with time to consider the request to participate and make a determination on whether to allow participation by the entity. In addition, current § 423.2010 addresses participation in Part D expedited appeals. Like proposed § 405.1010(a), we are proposing at § 423.2010(a) to provide CMS, the IRE, and the Part D plan sponsor with an opportunity to participate in the proceedings on a request for an ALJ hearing at two distinct points in the adjudication process, but the current policy of requiring the entity to request to participate is maintained. We are proposing at § 423.2010(b)(3)(i) and (ii) that, if no hearing is scheduled, CMS, the IRE and/or the Part D plan sponsor would have an initial opportunity to request to be a participant in an appeal within 30 calendar days after notification that a standard request for hearing was filed with OMHA, or within 2 calendar days after notification that a request for an expedited hearing was filed. The initial 30 calendar day period after notification that a standard request for hearing was filed with OMHA would be the same time frame provided under § 405.1010 for initial CMS and contractor elections, and we believe that 30 calendar day period after notification that a request for hearing was filed is sufficient time for CMS, the IRE, and the Part D plan sponsor to determine whether to request to be a participant in the proceedings and for the request to be considered and granted or denied as the case is reviewed to determine whether a decision may be appropriate based on the record in accordance with § 423.2038. We believe the 2 calendar day period after notification that an expedited request for hearing was filed is a reasonable period of time for CMS, the IRE, or the Part D plan sponsor to determine whether to request to be a participant in the proceedings given the 10-day adjudication time frame. We are proposing at § 423.2010(b)(3)(iii) and (iv) to provide a second opportunity to request to be a participant in an appeal if a hearing is scheduled. We are proposing at § 423.2010(b)(3)(iii) that if a non-expedited hearing is scheduled, CMS, the IRE, or the Part D plan sponsor would continue to have 5 calendar days after receiving the notice of hearing to make the request. We are proposing at § 423.2010(b)(3)(iv) that if an expedited hearing is scheduled, CMS, the IRE, or the Part D plan sponsor would continue to have 1 calendar day after receiving the notice of hearing to make the request. These time frames are carried over from current § 423.2010(b)(1) and (b)(3), and provide the ALJ with time to consider the request and notify the entity of his or her decision on the request to participate. As provided in current § 423.2010(a) and (g), we are proposing at § 423.2010(a)(2) to provide that an ALJ may request but may not require CMS, the IRE, or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any, and that the ALJ may not draw any adverse inferences if CMS, the IRE, or the Part D plan sponsor declines to be a participant to the proceedings.

The standards governing how an election is made in proposed § 405.1010(b) would be adopted in proposed § 423.2010(b) governing how a request to participate is made, except that an oral request to participate could be made for an expedited hearing, and OMHA would notify the enrollee of the request to participate in such cases.

Current § 423.2010(b)(2) and (b)(4) provide that an ALJ will notify an entity requesting to participate of the decision on the request within 5 calendar days for a request related to a non-expedited hearing, or 1 calendar day for a request related to an expedited hearing. These time frames would be incorporated in proposed § 423.2020(c). In addition, proposed § 423.2020(c)(1) would provide that if no hearing is scheduled, the notification is made at least 20 calendar days before the ALJ or attorney adjudicator (as proposed in section II.B above) issues a decision, dismissal, or remand. This would provide the participant with time to submit a position paper in accordance with proposed § 423.2010(d)(3)(i), as discussed below. Current § 423.2010(c) would also be incorporated into proposed § 423.2010(c), so that the provision clearly states that the assigned ALJ or attorney adjudicator (as proposed in section II.B above) has discretion to not allow CMS, the IRE, or the Part D plan sponsor to participate. Proposed § 423.2010(c) would provide that an attorney adjudicator as well as the ALJ may make a decision on a request to participate because a request to participate may be submitted for appeals that may be assigned to an attorney adjudicator and those appeals could also benefit from CMS, the IRE, or the Part D plan sponsor participation in the proceedings. We are not proposing to limit the number of participants in a hearing similar to proposed § 405.1010(d) because the ALJ has the discretion to deny a request to participate under § 423.1010 and may therefore deny a request to participate if the ALJ determines that a hearing would have sufficient participant involvement or does not need participant involvement.

We are proposing at § 423.2010(d) to consolidate current § 423.2010(d) through (f), to address the roles and responsibilities of CMS, the IRE, or the Part D plan sponsor as a participant. Specifically, we are proposing at § 423.2010(d)(1) to generally incorporate current § 423.2010(d), which provides that participation may include filing position papers or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, we are proposing in § 423.2010(d)(1) that participation may include filing position papers "and/or" providing testimony to emphasize that either or both may be done, and to remove the limitation that testimony must be written because participation may include providing oral testimony during the hearing. We are proposing at § 423.2010(d)(2) to incorporate current § 423.2010(e), which provides that when participating in a hearing, CMS, the IRE, or the Part D plan sponsor may not be called as a witness during the hearing and, thus, are not subject to examination or cross-examination by the enrollee at the hearing. However, to be clear about how an enrollee and the ALJ may address statements made by CMS, the IRE, or the Part D plan sponsor during the hearing given that limitation, we also are proposing in § 423.2010(d)(2) that the enrollee may rebut factual or policy statements made by the participant, and the ALJ may question the participant about its testimony.

We are proposing at § 423.2010(d)(3) to incorporate current § 423.2010(f) with certain revisions as discussed below. Current § 423.2010(f) states that CMS, the IRE, and/or the Part D plan sponsor must submit any position papers within the time frame designated by the ALJ. We are proposing in § 423.2010(d)(3) to include written testimony in the provision, establish deadlines for submission of position papers and written testimony that reflect the changes in participation elections in proposed 423.2010(b), and require that copies of position papers and written testimony be sent to the enrollee. Specifically, we are proposing in § 423.2010(d)(3) that, unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a CMS, the IRE, or the Part D plan sponsor position paper or written testimony must be submitted within 14 calendar days for a standard appeal or 1 calendar day for an expedited appeal after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled, or no later than 5 calendar days prior to a non-expedited hearing or 1 calendar day prior to an expedited hearing. We are proposing to add "written testimony" to recognize that CMS, the IRE, or the Part D plan sponsor or a contractor may submit written testimony as a participant, in addition to providing oral testimony at a hearing. We are proposing to require that position papers and written testimony be submitted within 14 calendar days for a standard appeal or 1 calendar day for an expedited appeal after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled to help ensure the position paper and/or written testimony are available when determinations are made to schedule a hearing or issue a decision based on the record in accordance with § 405.1038. We also are proposing to require that if a hearing is scheduled, position papers and written testimony be submitted no later than 5 calendar days prior to a non-expedited hearing or 1 calendar day prior to an expedited hearing (unless the ALJ grants additional time) to help ensure the ALJ and the enrollee have an opportunity to review the materials prior to the hearing. Similar to proposed § 405.1010(c)(3)(iii), we also are proposing at § 423.2010(d)(3)(ii) that a copy of the position paper or written testimony must be sent to the enrollee, and at § 423.2010(d)(iii) that a position paper or written testimony would not be considered in deciding an appeal if CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of the position paper or written testimony to the enrollee or fails to submit the position paper or written testimony within the established time frames. This would help ensure CMS, IRE, or Part D plan sponsor position papers and written testimony are submitted timely and shared with the enrollee.

Currently, there are no provisions in § 423.2010 to address the possibility of CMS, the IRE, and/or the Part D plan sponsor making an invalid request to participate. We are proposing to revise § 423.2010(e) to add new provisions to establish criteria for when a request to participate may be deemed invalid and provide standards for notifying the entity and the enrollee when a request to participate is deemed invalid. Proposed § 423.2010(e)(1) would provide that an ALJ or attorney adjudicator may determine a request to participate is invalid if the request to participate was not timely filed or the request to participate was not sent to the enrollee. This would help ensure that CMS, the IRE, and/or the Part D plan sponsor make timely requests to participate and inform the enrollee of requests. To provide notice to the entity and the enrollee that a request to participate was deemed invalid, proposed § 423.2010(e)(2) would require a written notice of an invalid request be sent to the entity that made the request and the enrollee. If no hearing is scheduled for the appeal or the request was made after the hearing occurred, proposed § 423.2010(e)(2)(i) would provide that the notice of an invalid request be sent no later than the date the decision, dismissal, or remand order is mailed. If a non-expedited hearing is scheduled for the appeal, proposed § 423.2010(e)(2)(ii) would provide that written notice of an invalid request is sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing, oral notice must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided. If an expedited hearing is scheduled for the appeal, proposed § 423.2010(e)(2)(iii) would provide that oral notice of an invalid request must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided. We are proposing to require the oral notice for expedited hearings because the very short time frames involved in expedited hearing proceedings often do not allow for delivery of a written notice and the oral notice will help ensure the entity is made aware of the invalid request prior to the hearing.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Section 423.2010: When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing" at the beginning of your comment.

iii. Section 405.1012: When CMS or Its Contractors May Be a Party to a Hearing

Current § 405.1012(a) states that CMS and/or its contractors may be a party to an ALJ hearing unless the request for hearing is filed by an unrepresented beneficiary. Current § 405.1012(b) states that CMS and/or the contractor(s) advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing. Current § 405.1012(c) states that, when CMS or its contractors participate in a hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or its contractor(s), when acting as parties, may also submit additional evidence to the ALJ within the time frame designated by the ALJ. Finally, current § 405.1012(d) states that the ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inferences if CMS or a contractor decides not to enter as a party. As stated previously, we are proposing significant changes to § 405.1012.

Current § 405.1012 does not limit the number entities that may elect to be a party to the hearing. This has resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections. To address these issues, we are proposing at § 405.1012(a)(1), except as provided in proposed paragraph (d) discussed below, to only allow either CMS or one of its contractors to elect to be a party to the hearing (unless the request for hearing is filed by an unrepresented beneficiary, which precludes CMS and its contractors from electing to be a party to the hearing). Current § 405.1012(b) states that CMS or a contractor advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing. We are proposing at § 405.1012(a) to incorporate and revise a portion of current § 405.1012(b), to require that an election to be a party must be filed no later than 10 calendar days after the QIC receives the notice of hearing, because notices of hearing are sent to the QIC in accordance with § 405.1020(c) (the remaining portion of current § 405.1012(b) is incorporated with revisions into proposed § 405.1012(b), as discussed below).

Current § 405.1012 does not have a provision similar to current § 405.1010(a), which states that an ALJ may request that CMS and/or one or more of its contractors participate in the proceedings, but current § 405.1012(d) does provide that the ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inference if CMS or a contractor decided not to enter as a party. In practice, ALJs do at times request that CMS or a contractor elect to be a party to the hearing, in conjunction with a request for participation under current § 405.1010(a). To align the provisions and reflect ALJ practices, we are proposing at § 405.1012(a)(2) to state that an ALJ may request but not require CMS and/or one or more of its contractors to be a party to the hearing. We also are proposing in § 405.1012(a)(2) to incorporate current § 405.1012(d) to provide that that an ALJ cannot draw any adverse inferences if CMS or a contractor decides not to enter as a party.

We are proposing at § 405.1012(b) to address how CMS or a contractor elects to be a party to the hearing. We are proposing to follow the same process in current § 405.1012(b) so that under proposed § 405.1012(b), CMS or the contractor would be required to send written notice of its intent to be a party to the hearing to the ALJ and the parties identified in the notice of hearing, which includes the appellant.

We are proposing to set forth the roles and responsibilities of CMS or a contractor as a party in § 405.1012(c). Proposed § 405.1012(c)(1) would incorporate current § 405.1012(c) with some changes in wording, both of which provide that as a party to the hearing, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses, or cross-examine the witnesses of other parties. We are proposing in § 405.1012(c)(2) to include written testimony, such as an affidavit or deposition, in the provision; establish deadlines for submission of position papers, written testimony, and evidence; and require that copies of position papers, written testimony, and evidence be sent to the parties that were sent a copy of the notice of hearing. Specifically, we are proposing in § 405.1012(c)(2)(i) and (c)(2)(ii) that any position papers, written testimony, and evidence must be submitted no later than 5 calendar days prior to the hearing, unless the ALJ grants additional time to submit the materials, and copies must be sent to the parties who were sent a copy of the notice of hearing. We are proposing to add "written testimony" to recognize that CMS or a contractor may submit written testimony, in addition to providing oral testimony at a hearing. We also are proposing to require that position papers, written testimony, and/or evidence be submitted no later than 5 calendar days prior to the hearing (unless the ALJ grants additional time), and that copies be submitted to the parties sent notice of the hearing, to help ensure the ALJ and the parties have an opportunity to review the materials prior to the hearing. Current § 405.1012 does not address the consequence of failure to submit a position paper or evidence in accordance with the section. We are proposing in § 405.1012(c)(2)(iii) that a position paper, written testimony, and/or evidence would not be considered in deciding an appeal if CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit the position paper, written testimony, and/or evidence within the established time frames. This would help ensure CMS or contractor position papers and evidence are submitted timely and shared with the parties.

As discussed above, current § 405.1012 does not limit the number entities (that is, CMS and its contractors) that may elect to be a party to the hearing and, as also discussed above, we are proposing to revise § 405.1010 and 405.1012 to limit the number of entities that participate in a hearing unless an ALJ determines that an entity's participation is necessary for a full examination of the matters at issue. We are proposing to revise § 405.1012(d)(1) to provide that if CMS and one or more contractors, or multiple contractors file elections to be a party to a hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under § 405.1010, subject to § 405.1010(d)(1) and (3) (and as such may file position papers and provide written testimony to clarify factual or policy issues in the case, but may not participate in the oral hearing unless the ALJ grants leave to the entity to participate in the oral hearing in accordance with § 405.1010(d)(3)). Similar to proposed § 405.1010(d)(3), we are also proposing in § 405.1012(d)(2) that, notwithstanding the limitation in proposed § 405.1012(d)(1), an ALJ may grant leave for additional entities to be parties to the hearing if the ALJ determines that an entity's participation as a party is necessary for full examination of the matters at issue.

We believe allowing the first entity to file an election after a notice of hearing is issued to be a party to the hearing is administratively efficient and provides an objective way to determine which entity is made a party based on the competing elections, while providing an opportunity to participate in the appeal by filing a position paper and/or written testimony under § 405.1010 for those that file later in time, or to be made a participant or party to the hearing by the ALJ under the ALJ's discretionary authority under proposed §§ 405.1010(d)(3) and 405.1012(d)(2). We considered an alternate proposal of the first entity that had elected participant status under § 405.1010, if any, being given priority for being made a party to the hearing, but believe that would result in other entities making a party election being uncertain whether they will be made a party to the hearing until as few as 5 days prior to the hearing (assuming the notice of hearing is sent 20 days prior to the scheduled hearing, as required by § 405.1022(a), the QIC receives the notice of hearing 5 days later, and the entity or entities responding to the notice of hearing can make their election as late as 10 calendar days after the QIC's receipt of the notice, leaving only 5 days prior to the hearing). We also considered a process by which the ALJ would assess which entity making a party election would be most helpful to the ALJ at the hearing, or in the alternative, permitting all entities that filed a party election to be made a party to the hearing unless the ALJ determined an entity is not necessary for the hearing, but both of these approaches would add administrative burden to the ALJ and could result in CMS, contractors and parties being uncertain of which entities will be parties to the hearing until shortly before the hearing. We welcome comments on the alternatives considered above.

Finally, we are proposing to add new § 405.1012(e) to address the possibility of CMS or a contractor making an invalid election. Proposed § 405.1012(e)(1) would provide that an ALJ or attorney adjudicator may determine an election is invalid if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue. This would help ensure that CMS and its contractors make timely elections and inform parties of elections, and also provide a mechanism to address an election when the request for hearing was filed by an unrepresented beneficiary or when another entity has already filed an election to be a party to the hearing. To provide notice to the entity and the parties that an election was deemed invalid, proposed § 405.1012(e)(2) would require a written notice of an invalid election be sent to the entity that made the election and the parties who were sent the notice of hearing. If the election was submitted after the hearing occurred, proposed § 405.1012(e)(2)(i) would provide that the notice of an invalid election be sent no later than the date the decision, dismissal, or remand notice is mailed. If the election was submitted before the hearing occurs, proposed § 405.1012(e)(2)(ii) would provide that the written notice of invalid election is sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice would be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing would be sent as soon as possible after the oral notice is provided.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Section 405.1012: When CMS or its contractors may be a party to a hearing" at the beginning of your comment.

g. Request for an ALJ Hearing or Review of a QIC or IRE Dismissal (§§ 405.1014, 423.1972 and 423.2014)

Current §§ 405.1014 and 423.2014 explain the requirements for requesting an ALJ hearing, including what must be contained in the request, when and where to file the request, the extension of time to request a hearing, and in § 405.1014 to whom a copy of the request for hearing must be sent. We are proposing to restructure the sections, clarify and provide additional instructions, and address other matters that have caused confusion for parties and adjudicators.

i. Requirements for a Request for Hearing or Review of a QIC or IRE Dismissal

We are proposing to revise the title and provisions of §§ 405.1014 and 423.2014 to more clearly cover a request for a review of a QIC or IRE dismissal. While the current requirements for requesting an ALJ hearing are generally used for requesting a review of a QIC or IRE dismissal in form HHS–725, we believe that explicitly extending §§ 405.1014 and 423.2014 to cover requests for these types of review would provide clarity to parties and adjudicators on the requirements for requesting a review of a QIC or IRE dismissal. As such, we are proposing in the title to § 405.1014 and in subsection (a)(1) (current subsection (a)) to add "or a review of a QIC dismissal" after "ALJ hearing," and in subsection (c) (current subsection (b)) to delete "after a QIC reconsideration" and add "or request for review of a QIC dismissal" after "an ALJ hearing." Similarly, we are proposing in the title to § 423.2014 and in subsection (a)(1) (current subsection (a)) to add "or a review of an IRE dismissal" after "ALJ hearing," and in subsection (d) (current subsection (c)) to add "or request for review of an IRE dismissal" after "IRE reconsideration."

We are proposing in § 405.1014(a)(1)(i) through (a)(1)(vi) to incorporate current § 405.1014(a)(1) through (a)(6) with revisions. In addition to the current requirements in subsection (a)(1), we are proposing in § 405.1014(a)(1)(i) to require the beneficiary's telephone number if the beneficiary is the filing party and is not represented. This would help ensure that OMHA is able to make timely contact with the beneficiary to clarify his or her filing, or other matters related to the adjudication of his or her appeal, including scheduling the hearing. We are proposing in § 405.1014(a)(1)(ii) to require the appellant's telephone number, along with the appellant's name and address as currently required in subsection (a)(2), when the appellant is not the beneficiary, and in § 405.1014(a)(1)(iii) to require a representative's telephone number, along with the representative's name and address which is currently included in subsection (a)(3), if a representative is involved. Like the beneficiary telephone number requirement, these requirements would help ensure that OMHA is able to make timely contact with a non-beneficiary appellant and any representative involved in the appeal to clarify the filing or other matters related to the adjudication of the appeal, including scheduling the hearing. Current subsection (a)(4) states that the request must include the document control number assigned to the appeal by the QIC, if any. We are proposing in § 405.1014(a)(1)(iv) to require the Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed, to reduce confusion for appellants. We are proposing in § 405.1014(a)(1)(v) to add language to the current language in subsection (a)(5), so that instead of requiring the "dates of service," we would require the "dates of service for the claims being appealed, if applicable," because an appellant may appeal some but not all of the partially favorable or unfavorable claims in a QIC reconsideration and a small number of appeals do not involve a date of service (for example, entitlement appeals). We are proposing to incorporate the same language in current subsection (a)(6) into proposed subsection (a)(1)(vi).

We are proposing to add a new requirement to the content of the request in § 405.1014(a)(1)(vii) by requiring a statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by the OIG or other law enforcement agencies. This information is necessary to assist OMHA staff in checking whether the provider or supplier was excluded from the program on the date of service at issue prior to scheduling a hearing or issuing a decision, as well as for the ALJ to determine whether to request the participation of CMS or any program integrity contractors that may have been involved in reviewing the claims below. However, we note that the information is only required if the filing party is aware of an investigation and proceeding, and the information would not be the basis for a credibility determination on evidence or testimony, as an investigation or allegations prior to findings of wrongdoing by a court of competent jurisdiction are not an appropriate foundation for credibility determinations in the context of part 405, subpart I administrative appeals.

As discussed in Section III.A.3.d above, we are proposing changes to the methodology for calculating the amount in controversy required for an ALJ hearing to better align the amount in controversy with the actual amount in dispute. We are also proposing new § 405.1014(a)(1)(viii) to require that providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency include in their request for hearing the amount in controversy applicable to the disputed claim, as specified in § 405.1006(d), unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services. As we discussed in section III.A.3.d., in instances where the Medicare allowable amount would serve as the basis for the amount in controversy (which we believe would be the majority of Part B appeals), we believe providers, suppliers, and Medicaid State agencies would be able to utilize existing CMS tools and resources to determine the allowable amount used as the basis for the amount in controversy under proposed § 405.1006(d)(2)(i)(A) and arrive at the amount in controversy after deducting any Medicare payments that have already been made or awarded and any deductible and/or coinsurance that may be collected for the items and services in the disputed claim. In addition, we believe that providers, suppliers, applicable plans, and Medicaid State agencies also would have access to the billing, payment and other necessary information to calculate the amount in controversy under other provisions of § 405.1006(d). For scenarios where the basis for the amount in controversy would be calculated in accordance with proposed § 405.1006(d)(2)(i)(B), (ii), (iii), or where the amount in controversy would be calculated in accordance with § 405.1006(d)(3), (5), (6), or (7), we discuss in section III.A.3.d above how appellants would determine the amount in controversy in order to include it on their request for hearing. However, because we believe there may be instances where a beneficiary who is not represented by a provider, supplier, or Medicaid State agency may not have the information necessary to determine the amount in controversy under § 405.1006(d) (as discussed above), we are not proposing to require beneficiaries who are not represented by a provider, supplier, or Medicaid State agency to include the amount in controversy in their requests for hearing. Furthermore, as noted above, we are not proposing that any appellant include the amount in controversy on requests for hearing where the amount in controversy would be calculated in accordance with § 405.1006(d)(4) (for a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services). We expect that, in this situation, a beneficiary could easily determine whether the minimum amount in controversy required for an ALJ hearing would be met through a conversation with the provider or supplier, or from the statement we are proposing the QIC include in its notice of reconsideration as discussed in section III.A.3.d above. However, we believe the exact amount in controversy could be difficult to determine because it may depend on unknown factors, such as the length of continued services that may be required, and so we are not requiring appellants to include this amount in the request for hearing.

Lastly, current § 405.1014(a)(7), which requires a statement of any additional evidence to be submitted and the date it will be submitted, would be separately designated in its entirety as proposed § 405.1014(a)(2) because the information in proposed § 405.1014(a)(1) must be present for a request for hearing to be processed and therefore would make the request subject to dismissal if the information is not provided, as discussed below. In contrast, the information in proposed § 405.1014(a)(2) is only necessary if evidence would be submitted and would not make the request subject to dismissal if not present in the request.

Similar to proposed § 405.1014(a), we are proposing at § 423.2014(a)(1)(i) through (a)(1)(vi) to incorporate current § 423.2014(a)(1) through (a)(6) with revisions. Current subsection (a)(3) states that the request must include the appeals case number assigned to the appeal by the IRE, if any. We are proposing in § 405.1014(a)(1)(iii) to revise the requirement to state that the request must include the Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed, to reflect the terminology used by the IRE and thereby reduce confusion for enrollees. Current subsection (a)(6) states that the request must include the reasons the enrollee disagrees with the IRE's reconsideration. We are proposing to insert "or dismissal" after "reconsideration" to again reflect the terminology used by the IRE and thereby reduce confusion for enrollees. For the same reasons as we proposed for § 405.1014(a)(1)(vii), we are proposing at § 423.2014(a)(1)(vii) to require a statement of whether the enrollee is aware that he or she, or the prescription for the drug being appealed, is the subject of an investigation or proceeding by the OIG or other law enforcement agencies. In addition, we are proposing at § 423.2014(a)(2) to incorporate the current § 423.2014(a)(7) requirement to include a statement of any additional evidence to be submitted and the date it will be submitted, and at § 423.2014(a)(3) to incorporate the current § 423.2014(a)(8) requirement to include a statement that the enrollee is requesting an expedited hearing, if applicable.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Requirements for a request for hearing or review of a QIC or IRE dismissal" at the beginning of your comment.

ii. Requests for Hearing Involving Statistical Sampling and Extrapolations

We are proposing to add new § 405.1014(a)(3) to address appeals in which an appellant raises issues regarding a statistical sampling methodology and/or an extrapolation that was used in making an overpayment determination. OMHA has encountered significant issues when an appellant challenges aspects of a statistical sampling methodology and/or the results of extrapolations in separate appeals for each sampled claim involved in the statistical sampling and/or extrapolation. Appeals often need to be reassigned to avoid multiple adjudicators addressing the challenges to the statistical sampling methodology and/or extrapolation, and any applicable adjudication time frames attach to the individual appeals. Under proposed § 405.1014(a)(3), if an appellant is challenging the statistical sampling methodology and/or extrapolation, the appellant's request for hearing must include the information in proposed § 405.1014(a)(1) and (a)(2) for each sample claim that the appellant wishes to appeal, be filed within 60 calendar days of the date that the party received the last reconsideration for the sample claims (if they were not all addressed in a single reconsideration), and assert the reasons the appellant disagrees with the statistical sampling methodology and/or extrapolation in the request for hearing. We believe it would be appropriate in this situation to allow the appellant's request for hearing to be filed within 60 calendar days of the date that the party received the last reconsideration for the sample claims (if they were not all addressed in a single reconsideration), because if the appellant also wishes to challenge the statistical sampling methodology and/or extrapolation, the appellant would wait to file a request for hearing until all of the QIC reconsiderations for the sample units are received, which could be more than 60 calendar days after the first received QIC reconsideration of one of the sample claims. We also state that the 60 calendar day period in proposed § 405.1014(a)(3)(ii) would begin on the date the party receives the last reconsideration of a sample claim, regardless of the outcome of the claim in the reconsideration or whether the sample claim is appealed in the request for hearing. We believe proposed § 405.1014(a)(3) would balance the party's rights to request a hearing on individual claims when only the sample claims are appealed, with the needs to holistically address issues related to statistical sampling methodologies and extrapolations when those determinations are also challenged. We are not proposing any corresponding changes to § 423.2014 because sampling and extrapolation are not currently used in Part D appeals.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Requests for hearing involving statistical sampling and extrapolations" at the beginning of your comment.

iii. Opportunity To Cure Defective Filings

There has been considerable confusion on the implications of not providing the information required by current § 405.1014(a) in order to perfect a request for hearing, and significant time and resources have been spent on this procedural matter by parties, OMHA, and the Council. To provide clearer standards and reduce confusion, we are proposing in § 405.1014(b)(1) that a request for hearing or request for a review of a QIC dismissal must contain the information specified in proposed § 405.1014(a)(1) to the extent the information is applicable, to be complete, and § 405.1014(b)(1) would provide that any applicable adjudication time frame does not begin until the request is complete because the information is necessary to the adjudication of the appeal. We are proposing in § 405.1014(b)(1) to also provide an appellant with an opportunity to complete the request if the request is not complete. However, if the appellant fails to provide the information necessary to complete the request in the time frame provided, the request would not be complete and would be dismissed in accordance with proposed § 405.1052(a)(7) or (b)(4). We are also proposing at § 405.1014(b)(2) to allow for consideration of supporting materials submitted with a request when determining whether the request is complete, provided the necessary information is clearly identifiable in the materials, to provide that an appellant's request and supporting materials is considered in its totality. For example, if an appellant were to submit a request for hearing and included a copy of the QIC reconsideration, the Medicare appeal number on the QIC reconsideration would generally satisfy the subsection (a)(1)(iv) requirement because it clearly provides the information. However, if there are multiple claims in the QIC reconsideration, the same document possibly would not satisfy subsection (a)(1)(v) because the appellant is not required to appeal all partially favorable or unfavorable claims, and subsection (a)(1)(v) requires the appellant to indicate the dates of service for the claims that are being appealed. Similarly, including medical records only for the dates of service that the appellant wishes to appeal would generally not satisfy subsection (a)(1)(v) because it would be unclear whether the appellant intended to limit the appeal to only those dates of service for which medical records were included, or those were the only dates of service for which the appellant had medical records. We are proposing that the provisions of proposed § 405.1014(b) be adopted in proposed § 423.2014(c) for requesting an ALJ hearing or a review of an IRE dismissal in Part D appeals.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Opportunity to cure defective filings" at the beginning of your comment.

iv. Where and When To File a Request for Hearing or Review of a QIC or IRE Dismissal

We are proposing to incorporate portions of current § 405.1014(b) in proposed § 405.1014(c) and portions of current § 423.2014(c) in proposed § 423.2014(d) to address when and where to file a request for hearing or review. We are proposing in §§ 405.1014(c) introductory language and (c)(1), and 423.2014(d) introductory language and (d)(1), to incorporate a request for a review of a QIC dismissal and a request for a review of an IRE dismissal, respectively, and provide that the current 60 calendar day period to file a request for hearing after a party receives a QIC or an IRE reconsideration also applies after a party receives a QIC or IRE dismissal, which is the time frame stated in §§ 405.1004 and 423.2004 to request a review of a QIC or IRE dismissal, respectively. We also are proposing in § 405.1014(c)(1) to add an exception for requests filed in accordance with proposed § 405.1014(a)(3)(ii), because as discussed above, we are proposing to require that requests for hearing on sample claims that are part of a statistical sample and/or extrapolation that the appellant also wishes to challenge would be filed together, which may be more than 60 calendar days after the appellant receives the first QIC reconsideration of one of the sample claims. In addition, we are proposing to revise the statement that a request must be "submitted" in current § 423.2014(c)(1), with a request must be "filed" in § 423.2014(d)(1), for consistency with § 405.1014 and § 422.602, both of which use the term "filed." We are also proposing in §§ 405.1014(c)(2) and 423.2014(d)(2) to replace references to sending requests to the "entity" specified in the QIC's or IRE's reconsideration in current §§ 405.1014(b)(2) and 423.2014(c)(2), with sending requests to the "office" specified in the QIC's or IRE's reconsideration or dismissal, respectively, so they are properly routed. As discussed in III.A.3.b. and III.A.3.c, above, regarding proposed

§§ 405.1002 and 405.1004, and 423.2002 and 423.2004, replacing "entity" with "office" in §§ 405.1014, 423.1972, and 423.2014 would help ensure appellants are aware that a request for hearing or request for a review of a QIC or IRE dismissal must be filed with the office indicated in the QIC's or IRE's reconsideration or dismissal and avoid delays. However, we again note that for the few requests for hearing that are misrouted by a party, a notice would be sent to the appellant when the request for hearing is received in the correct office and the date the timely request was received by the incorrect office would be used to determine the timeliness of the request, in accordance with proposed §§ 405.1014(c)(2) and 423.2014(d)(2)(i), which would incorporate the misrouted request provisions from current §§ 405.1014(b)(2) and 423.2014(c)(2)(i). We are also proposing in §§ 405.1014(c)(2) and 423.2014(d)(2)(i) that the adjudication time frame is only affected if there is an applicable adjudication time frame for the appeal.

Current § 423.1972(b) states that an enrollee must file a request for a hearing within 60 calendar days of the date of the notice of the IRE reconsideration determination. This requirement differs from § 423.2002(a)(1), which states that a request for hearing must be filed within 60 calendar days after receipt of the IRE's reconsideration (this is also the standard for filing Part A and Part B requests for hearing after receipt of QIC reconsiderations, at § 405.1002(a)(1). We are proposing to revise § 423.1972(b)(1) to state that a request for hearing must be filed within 60 calendar days after receipt of the IRE's reconsideration. We also are proposing to add new § 423.1972(b)(2), to incorporate current § 423.2002(d), which provides the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the written reconsideration unless there is evidence to the contrary (this is also a presumption for receipt of QIC reconsiderations in Part A and Part B appeals, at § 405.1002). These changes would align proposed § 423.1972(b) with current § 423.2002, and remove potential enrollee confusion on when a request for an ALJ hearing must be filed.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Where and when to file a request for hearing or review of a QIC or IRE dismissal" at the beginning of your comment.

v. Sending Copies of a Request for Hearing and Other Evidence to Other Parties to the Appeal

We are proposing to incorporate the portion of current § 405.1014(b)(2) that states that the appellant must also send a copy of the request for hearing to the other parties and failure to do so will toll the ALJ's 90 calendar day adjudication deadline until all parties to the QIC reconsideration receive notice of the requested ALJ hearing in proposed § 405.1014(d) with changes discussed below. Current § 405.1014(b)(2) has been another source of considerable confusion, and significant time and resources have been spent on this procedural matter by parties, OMHA, and the Council. Current § 405.1014(b)(2) requires an appellant to send a copy of the request for hearing to the other parties. Other parties consist of all of the parties specified in § 405.906(b) as parties to the reconsideration, including beneficiaries in overpayment cases that involve multiple beneficiaries who have no liability, in which case the QIC may elect to only send a notice of reconsideration to the appellant, in accordance with § 405.976(a)(2). We are proposing in § 405.1014(d)(1) to amend the current copy requirement by only requiring an appellant to send a copy of a request for an ALJ hearing or review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. This change would make the standard consistent with requests for Council review, a copy of which must be sent by the appellant to the other parties who received a copy of an ALJ's decision or dismissal, in accordance with current § 405.1106(a). This change would also extend the requirement to requests for review of a QIC dismissal to provide the other parties who received notice of the QIC's dismissal action with notice of the appellant's appeal of that action.

We are also proposing in § 405.1014(d)(1) to address whether copies of materials that an appellant submits with a request for hearing or request for review of a QIC dismissal must be sent to other parties. Currently some ALJs consider the materials to be part of the request and require an appellant to send copies of all materials submitted with a request, while other ALJs do not consider the materials to be part of the request. We are proposing in § 405.1014(d)(1) that if additional materials submitted with a request are necessary to provide the information required for a complete request in accordance with proposed § 405.1014(b), copies of the materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). If additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence). For example, if a complete request includes a position paper or brief that explains the reasons the appellant disagrees with the QIC's reconsideration, in accordance with proposed § 405.1014(a)(1)(v), a copy of the position paper or brief would be sent to the other parties, subject to any authorities that apply to disclosing the personal information of other parties. However, additional evidence such as medical records, is generally not required for a complete request, and therefore copies would not have to be sent, but could instead be summarized and provided to the other parties at their request, again subject to any authorities that apply to disclosing the personal information of other parties. This approach would balance the objectives of ensuring that parties to a claim and an appeal of that claim remain informed of the proceedings that are occurring on the claim, with the burdens on appellants to keep their co-parties so informed. We also note that in sending a copy of the request for hearing and associated materials, appellants are free to include cover letters to explain the request, but we note that such letters on their own do not satisfy the copy requirement in its current or proposed form. No corresponding changes are proposed in § 423.2014 because the enrollee is the only party to the appeal.

Current § 405.1014 does not contain standards for what constitutes evidence that a copy of the request for hearing or review, or copy of the evidence or a summary thereof, was sent to the other parties, which has led to confusion and inconsistent practices. Therefore, we are proposing in § 405.1014(d)(2) to address this issue by establishing standards that an appellant would follow to satisfy the requirement. We are proposing in § 405.1014(d)(2) that evidence that a copy of the request for hearing or review, or a copy of submitted evidence or a summary thereof, was sent includes: (1) Certifications that a copy of the request for hearing or request for review of a QIC dismissal is being sent to the other parties on the standard form for requesting a hearing or review of a QIC dismissal; (2) an indication, such as a copy or "cc" line on a request for hearing or review, that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipients; (3) an affidavit or certificate of service that identifies the name and address of the recipient and what was sent to the recipient; or (4) a mailing or shipping receipt that identifies the name and address of the recipient and what was sent to the recipient. We believe these options would provide an appellant with flexibility to document the copy requirement was satisfied and bring consistency to the process.

Beyond stating that an adjudication time frame is tolled if a party does not satisfy the copy requirement, current § 405.1014 does not address the consequence of not satisfying the requirement, and adjudicators are faced with an appeal being indefinitely tolled because an appellant refuses to comply with the requirement. OMHA ALJs have addressed this issue by providing appellants with an opportunity to send the required copy of the request for hearing, and by informing the appellant that if the copy is not sent, its request will be dismissed. This allows OMHA ALJs to remove requests that do not satisfy the requirement from their active dockets so time and resources can be focused on appeals of those who comply with the rules. We are proposing in § 405.1014(d)(3) that, if the appellant fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of the submitted evidence or a summary thereof, the appellant would be provided with an opportunity to cure the defects by sending the request, materials, and/or evidence or summary thereof described in proposed subsection (d)(1). Further, proposed § 405.1014(d)(3) would provide that if an adjudication time frame applies, it does not begin until evidence that the request, materials, and/or evidence or summary thereof were sent is received. We are also proposing in § 405.1014(d)(3) that if an appellant does not provide evidence within the time frame provided to demonstrate that the request, materials, and/or evidence or summary thereof were sent to other parties, the appellant's request for hearing or review would be dismissed.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Sending copies of a request for hearing and other evidence to other parties to the appeal" at the beginning of your comment.

vi. Extending Time To File a Request for Hearing or Review of a QIC or IRE Dismissal

We are proposing that the provisions of current §§ 405.1014(c) and 423.2014(d) for extensions of time to file a request for hearing would be incorporated in proposed §§ 405.1014(e) and 423.2014(e) with changes, and would extend to requests for reviews of QIC and IRE dismissals. On occasion, OMHA is asked whether a request for an extension should be filed without a request for hearing, for a determination on the request for extension before the request for hearing is filed. In those instances, we ask the filer to file both the request for hearing and request for extension at the same time because an independent adjudication of the extension request would be inefficient and any adjudication time frame begins on the date that the ALJ grants the extension request, in accordance with current §§ 405.1014(c)(4) and 423.2014(d)(4). We are proposing in §§ 405.1014(e)(2) and 423.2014(e)(3) to require a request for an extension be filed with the request for hearing or request for review of a QIC or IRE dismissal, with the office specified in the notice of reconsideration or dismissal. Proposed §§ 405.1014(e)(2) and 423.2014(e)(3) would also align the provision with proposed §§ 405.1014(c) and 423.2014(d) by specifying that a request for an extension must be filed with the "office," rather than the "entity," specified in the notice of reconsideration. We are proposing in § 405.1014(e)(3) and 423.2014(e)(4) that an ALJ or attorney adjudicator may find good cause to extend the deadline to file a request for an ALJ hearing or a request for a review of a QIC or IRE dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC or IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. Because only an ALJ may dismiss a request for an ALJ hearing for an untimely filing in accordance with proposed §§ 405.1052 and 423.2052, an attorney adjudicator could not make a determination on a request for an extension that would result in a dismissal of a request for hearing. We are also proposing to incorporate current §§ 405.1014(c)(4) and 423.2014(d)(5) into proposed §§ 405.1014(e)(4) and 423.2014(e)(5), but indicate that the adjudication time frame begins on the date the ALJ or attorney adjudicator grants the request to extend the filing deadline only if there is an applicable adjudication period. Finally, we are proposing in §§ 405.1014(e)(5) and 423.2014(e)(6) to add a new provision to provide finality for the appellant with regard to a determination to grant an extension of the filing deadline. We are proposing that if an ALJ or attorney adjudicator were to make a determination to grant the extension, the determination is not subject to further review. However, we are not precluding review of a determination to deny an extension because such a denial would result in a dismissal for an untimely filing, and the dismissal and determination on the request for an extension would be subject to review by the Council.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Extending time to file a request for hearing or review of a QIC or IRE dismissal" at the beginning of your comment.

h. Time Frames for Deciding an Appeal of a QIC or IRE Reconsideration or an Escalated Request for a QIC Reconsideration, and Request for Council Review When an ALJ Does Not Issue a Decision Timely (§§ 405.1016, 405.1104 and 423.2016)

i. Section 405.1016: Time frames for Deciding an Appeal of a QIC or an Escalated Request for a QIC Reconsideration

Current § 405.1016 addresses the adjudication time frames for requests for hearing filed after a QIC has issued its reconsideration, in accordance with section 1869(d)(1)(A) of the Act, and escalations of requests for a QIC reconsideration when the QIC does not issue its reconsideration within its adjudication time frame, which is permitted by section 1869(c)(3)(C)(ii) of the Act. We are proposing to revise the title of § 405.1016 from "Time frames for deciding an appeal before an ALJ" to "Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration" because the section specifically applies to appeals of QIC reconsiderations and escalated requests for QIC reconsiderations (as specified in current and proposed § 405.1016(a) and (c)). This revision would also allow for application of this section to requests for hearing adjudicated by attorney adjudicators, as proposed in Section II.B. above. We also are proposing to replace each instance of the term "the ALJ" with "the ALJ or attorney adjudicator" throughout proposed § 405.1016 to assist appellants in understanding that an adjudication time frame, and the option to escalate, also would apply to a request for an ALJ hearing following a QIC reconsideration when the request has been assigned to an attorney adjudicator, as proposed in section II.B, above. We are not proposing to change the reference to "a request for an ALJ hearing" because, as explained above in section II.B, even if an appellant waives its right to hearing, the case would remain subject to a potential oral hearing before an ALJ, and we believe the request is therefore properly characterized as a request for an ALJ hearing.

We are proposing to add titles to proposed § 405.1016(a) to indicate that this paragraph discusses the adjudication period for appeals of QIC reconsiderations, and proposed § 405.1016(c) to indicate that this paragraph discusses the adjudication period for escalated requests for QIC reconsiderations. In addition, proposed § 405.1016(a) and (c) would remove "must," in providing that when a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration. While the statute envisions that appeals will be adjudicated within the statutory time frame, the statute also provides for instances in which the adjudication time frame is not met by allowing an appellant to escalate his or her appeal to the next level of appeal. We believe "must" should be reserved for absolute requirements, and in the context of adjudication time frames, the statute provides the option for an appellant to escalate an appeal if the adjudication time frame is not met.

We are proposing to add a title to proposed § 405.1016(b) to indicate that the paragraph discusses when an adjudication period begins. Current § 405.1016(b), which explains that the adjudication period for an appeal of a QIC reconsideration begins on the date that a timely filed request for hearing is received unless otherwise specified in the subpart, would be re-designated as proposed § 405.1016(b)(1). We are proposing in § 405.1016(b)(2) that if the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c), the remanded appeal would be subject to the adjudication time frame of § 405.1016(a) beginning on the date that OMHA receives the Council remand. Currently the regulations do not address whether an adjudication time frame applies to appeals that are remanded from the Council, and whether escalation is an option for these appeals. To provide appellants with an adjudication time frame for remanded appeals that were subject to an adjudication time frame when they were originally appealed to OMHA, proposed § 405.1016(b)(2) would apply the adjudication time frame under § 405.1016(a) to a remanded appeal that was subject to an adjudication time frame under paragraph (a) or (c). For example, if an ALJ decision reviewed by the Council involved a QIC reconsideration and was remanded by the Council, a 90 calendar day time frame would apply from the date that OMHA received the remand order. If the adjudication time frame is not met under proposed § 405.1016(b)(2), the appeal would be subject to escalation, in accordance with proposed § 405.1016(e).

In addition, we are proposing in § 405.1016(a) and (b) to align the paragraphs with proposed § 405.1014(c) by specifying that a request for hearing is received by the "office," rather than the "entity," specified in the QIC's notice of reconsideration.

We are proposing to add a title to proposed § 405.1016(d) to indicate that the paragraph discusses waivers and extensions of the adjudication period. We are proposing in § 405.1016(d)(1) to incorporate the adjudication period waiver provision in current § 405.1036(d), which states that, at any time during the hearing process, the appellant may waive the adjudication deadline specified in § 405.1016 for issuing a hearing decision, and that the waiver may be for a specific period of time agreed upon by the ALJ and the appellant. We are proposing to move the provision because we believe it is more appropriately addressed in § 405.1016, as it is directly related to the adjudication period. Proposed § 405.1016(d) would also revise the language in current § 405.1036(d) to reference an attorney adjudicator consistent with our proposals in Section II.B. above; to reference the "adjudication" process rather than the "hearing process" to account for appeals that may not involve a hearing, to consistently reference an adjudication "period" for internal consistency, and to replace the reference to § 405.1016 with internal paragraph references.

Current § 405.1016 does not address delays that result from stays ordered by U.S. Courts. In addition, we have had instances in which an appellant requests a stay of action on his or her appeals while related matters are addressed by another court or tribunal, or by investigators. To address these circumstances, we are proposing in § 405.1016(d)(2) that the adjudication periods specified in paragraphs (a) and (c) are extended as otherwise specified in this subpart, and for the duration of any stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction, or the duration of any stay of proceedings granted by an ALJ or attorney adjudicator on the motion of the appellant, provided no other party also filed a request for hearing on the same claim at issue.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Section 405.1016: Time frames for deciding an appeal of a QIC or an escalated request for a QIC reconsideration" at the beginning of your comment.

ii. Incorporation of the Provisions of Section 405.1104 (Request for Council Review When an ALJ Does Not Issue a Decision Timely) Into Section 405.1016(f)

Current § 405.1104 addresses how to request escalation from an ALJ to the Council, when an ALJ has not issued a decision, dismissal or remand on a QIC reconsideration within an applicable adjudication time frame, in accordance with section 1869(d)(3)(A) of the Act in paragraph (a); the procedures for escalating an appeal in paragraph (b); and the status of an appeal for which the adjudication time frame has expired but the appellant has not requested escalation in paragraph (c). We are proposing to remove and reserve § 405.1104 and incorporate the current § 405.1104 providing for escalating a request for an ALJ hearing to the Council into proposed § 405.1016(e) and (f) with revisions, as its current placement in the Council portion of part 405, subpart I has caused confusion. We also are proposing to insert "or attorney adjudicator" after "ALJ" in proposed § 405.1016(e) and (f) to assist appellants in understanding that the effect of exceeding the adjudication period and the option to escalate would apply to a request for an ALJ hearing following a QIC reconsideration when the request has been assigned to an attorney adjudicator, as discussed in section II.B, above.

Current § 405.1104(c) is titled "No escalation" and states that if the ALJ's adjudication period set forth in § 405.1016 expires, the case remains pending with the ALJ until a decision, dismissal order, or remand order is issued or the appellant requests escalation to the Council. We are proposing in § 405.1016(e) to incorporate current § 405.1104(c) with changes. We are proposing to revise the paragraph title for proposed § 405.1016(e) to indicate that the paragraph discusses the effect of exceeding the adjudication period. Proposed § 405.1016(e) would provide that if an ALJ or an attorney adjudicator assigned to a request for hearing (as proposed in section II.B above) does not issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in the section, the party that filed the request for hearing may escalate the appeal when the adjudication period expires. However, if the adjudication period expires and the party that filed the request for hearing does not exercise the option to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand. We are proposing to indicate that the appeal remains pending with OMHA to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned.

Current § 405.1104(a) describes how to request an escalation and states that an appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period may request Council review if the appellant files a written request with the ALJ to escalate the appeal to the Council after the adjudication period has expired, and the ALJ does not issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016. We are proposing in § 405.1016(f)(1) to remove the requirement to request Council review in the course of requesting an escalation and to describe when and how to request escalation. Specifically, we are proposing to revise the current procedures at § 405.1104(a) and (a)(1), to provide that an appellant who files a timely request for a hearing with OMHA and whose appeal continues to be pending at the end of an applicable adjudication period may exercise the option to escalate the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council, which would simplify the process for appellants and adjudicators by only requiring appellants to file a single request for escalation with OMHA. We are proposing to replace the reference to an appeal that "continues to be pending before the ALJ" in current § 405.1104(a) with an appeal that "continues to be pending with OMHA" in proposed § 405.1016(f)(1) to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned. We are also proposing that a written request to escalate an appeal to the Council would be filed with OMHA to allow OMHA to provide a central filing option for escalation requests. Current § 405.1106(b) requires that the appellant send a copy of the escalation request to the other parties and failing to do so tolls the Council's adjudication deadline set forth in § 405.1100 until the other parties to the hearing have received notice. As discussed in section III.A.5.c below, we are proposing to revise § 405.1106(b) to require that the request for escalation be sent to other parties who were sent a copy of the QIC reconsideration. Therefore, we are also proposing at § 405.1016(f)(1) that the appellant would send a copy of the escalation request to the other parties who were sent a copy of the QIC reconsideration so appellants would be aware of the requirement and which parties must be sent a copy of the escalation request.

Current § 405.1104(b) describes the escalation process and states if the ALJ is not able to issue a decision, dismissal order, or remand order within the time period set for in paragraph (a)(2) of the section (later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016), he or she sends notice to the appellant acknowledging receipt of the request for escalation and confirming that the ALJ is not able to issue a decision, dismissal order, or remand order within the statutory time frame, or if the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of the section or does not send the required notice to the appellant, the QIC decision becomes the decision that is subject to Council review consistent with § 405.1102(a). This process has caused confusion for both appellants and adjudicators because an initial escalation request must be filed with the ALJ, and if the ALJ is unable to issue a decision, dismissal or remand within 5 calendar days of receiving the escalation request or within 5 calendar days from the end of the applicable adjudication period, the appellant must file a request for Council review to move the appeal to the Council level, which some appellants do not file. This leaves it unclear to the ALJ and support staff whether to continue adjudicating the appeal after issuing a notice that the ALJ is unable to issue a decision, dismissal or remand within 5 calendar days of receiving the escalation request. We are proposing in § 405.1016(f)(2) to revise the escalation process. Specifically, we are proposing that if an escalation request meets the requirements of proposed § 405.1016(f)(1), and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period, OMHA (to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned) would send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of § 405.1016. We also are proposing that the notice would state that the QIC reconsideration would be the decision that is subject to Council review consistent with § 405.1102(a); and the appeal would be escalated to the Council in accordance with § 405.1108. OMHA would then forward the case file, which would include the file received from the QIC and the request for escalation and all other materials filed with OMHA, to the Council. We believe that this proposed process would help alleviate the current confusion, and would simplify the escalation process for appellants because appellants would not have to file a separate request for Council review after filing an escalation request with OMHA.

Currently, invalid escalation requests are not addressed in the regulations. We are proposing in § 405.1016(f)(3) to address invalid escalation requests. We are proposing that if an ALJ or attorney adjudicator determines an escalation request does not meet the requirements of proposed § 405.1016(f)(1), OMHA would send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation. For example, an escalation request would be deemed invalid if escalation is not available for the appeal, such as appeals of SSA reconsiderations; the escalation request is premature because the adjudication period has not expired; or the party that filed the escalation request did not file the request for hearing. If an ALJ or attorney adjudicator were to determine the request for escalation was invalid for a reason that could be corrected (for example, if the request was premature), the appellant could file a new escalation request when the adjudication period expires.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Section 405.1016: Escalation of a request for an ALJ hearing" at the beginning of your comment.

iii. Section 423.2016: Time frames for Deciding an Appeal of an IRE Reconsideration

Current § 423.2016 addresses the adjudication time frames for requests for hearing filed after an IRE has issued its reconsideration. The title of current § 423.2016 states, "Timeframes for deciding an Appeal before an ALJ." We are proposing to revise the title of § 423.2016 to read "Time frames for deciding an appeal of an IRE reconsideration" in order to state that the section addresses adjudication time frames related to appeals of IRE reconsiderations and to accommodate the application of this section to attorney adjudicators, as proposed in Section II.B. above, and as discussed earlier. We also are proposing to insert "or attorney adjudicator" after "ALJ" throughout proposed § 423.2016 so that an adjudication time frame would apply to a request for an ALJ hearing following an IRE reconsideration when the request has been assigned to an attorney adjudicator, as discussed in section II.B, above.

Current § 423.2016(a) and (b) explain the adjudication time frames for standard and expedited appeals of IRE reconsiderations, respectively. However, the current paragraph titles refer to hearings and expedited hearings. We are proposing at § 423.2016(a) and (b) to retitle the paragraphs to refer to standard appeals and expedited appeals because the time frames apply to issuing a decision, dismissal, or remand, and are not limited to appeals in which a hearing is conducted. Similar to proposed § 405.1016, we are proposing at § 423.2016(a) and (b) to remove "must" in providing when an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the IRE, as appropriate, after the request for hearing is received by the office specified in the IRE's notice of reconsideration because there may be instances in which a decision, dismissal, or remand cannot be issued within the adjudication time frame, though we expect those instances to be rare because beneficiary and enrollee appeals are generally prioritized by OMHA. In addition, we are proposing in § 423.2016(a) and (b) to replace references to sending a request to the "entity" specified in the IRE's reconsideration, with the "office" specified in the IRE's reconsideration notice, to minimize confusion and delays in filing requests with OMHA. Similar to proposed § 405.1016(b)(2), we are proposing at § 423.2016(a)(3) and (b)(6) to adopt adjudication time frames for appeals that are remanded by the Council. Specifically, we are proposing in § 423.2016(a)(3) that if the Council remands a case and the case was subject to an adjudication time frame, the remanded appeal would be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand to provide enrollees with an adjudication time frame for remanded appeals. In § 423.2016(b)(6), we are proposing to require that if the standards for an expedited appeal continue to be met after the appeal is remanded from the Council, the 10-day expedited time frame would apply to an appeal remanded by the Council. If the standards for an expedited appeal are no longer met, the adjudication time frame for standard appeals would apply because the criteria for an expedited hearing are no longer present. Finally, we are proposing at § 423.2016(b) to revise the expedited appeal request process to permit an ALJ or attorney adjudicator to review a request for an expedited hearing, but not require the same ALJ or attorney adjudicator to adjudicate the expedited appeal, to provide OMHA with greater flexibility to review and assign requests for expedited hearings, and help ensure the 10-day adjudication process is completed as quickly as the enrollee's health requires. For example, if an attorney adjudicator were to review a request for an expedited hearing and determine that the standards for an expedited hearing were met, but did not believe a decision could be issued without a hearing, the attorney adjudicator could provide the enrollee with notice that the appeal would be expedited and transfer the appeal to an ALJ for an expedited hearing and decision.

As described in section III.A.3.q below, we are proposing to move the provision for waiving the adjudication period from current § 423.2036(d) to proposed § 423.2016(c) because proposed § 423.2016 addresses adjudication time frames and we believe the section is a better place for discussing adjudication time frame waivers.

We are proposing that the provisions of proposed § 405.1016(d) be adopted in proposed § 423.2016(c) for adjudication period waivers and stays of the proceedings ordered by a court or granted by an ALJ or attorney adjudicator on motion by an enrollee.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Section 423.2016: Time frames for deciding an appeal of an IRE reconsideration" at the beginning of your comment.

i. Submitting Evidence (§§ 405.1018 and 423.2018)

Current §§ 405.1018 and 423.2018 address submitting evidence before an ALJ hearing is conducted. We are proposing to retitle the sections from "Submitting evidence before the ALJ hearing" to "Submitting evidence" because evidence may be submitted and considered in appeals for which no hearing is conducted by an ALJ, and we believe an attorney adjudicator should be able to consider submitted evidence in deciding appeals as proposed in section II.B above. For the same reason, we are proposing in § 423.2018 to replace the references to "hearings" in the heading to paragraph (a) and in the introductory text to paragraphs (b) and (c), with "appeals." We are also proposing to add headings to paragraphs that do not currently have headings, for clarity of the matters addressed in the paragraphs.

Current § 405.1018(a) states that, except as provided in this section, parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 calendar days of receiving the notice of hearing). We are proposing in § 405.1018(a) to provide for the submission of other evidence, in addition to written evidence, that the parties wish to have considered. Other evidence could be images or data submitted on electronic media. This revision would also be adopted in proposed § 405.1018(b) and § 423.2018(a), (b), and (c). We are also proposing in § 405.1018(a) to remove "at the hearing" so that parties would submit all written or other evidence they wish to have considered, and consideration of the evidence would not be limited to the hearing. We are proposing a corresponding change at proposed § 423.2018(a).

Current § 405.1018(a) states that evidence must be submitted with the request for hearing, or within 10 calendar days of receiving the notice of hearing. This provision has caused confusion as to when evidence is required to have been submitted because current § 405.1014(a)(7) allows an appellant to state in the request for hearing that additional evidence will be submitted and the date it will be submitted. To reconcile the provisions, we are proposing in § 405.1018(a) to provide that parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with proposed § 405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing. We also are proposing that these revisions would be adopted in proposed § 423.2018(b) and (c).

Current § 405.1018(b) addresses how the submission of evidence impacts the adjudication period, and provides that if evidence is submitted later than 10 calendar days after receiving the notice of hearing, the period between when the evidence "was required to have been submitted" and the time it is received does not count towards an adjudication period. To simplify the provision, we are proposing at § 405.1018(b) that if evidence is submitted later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received. This revision would also be adopted in proposed § 423.2018(b)(2) and (c)(2), except that in (c)(2), the adjudication time frame is affected if the evidence is submitted later than 2 calendar days after receipt of the notice of expedited hearing because 2 calendar days is the equivalent time frame to submit evidence for expedited appeals before the adjudication period is affected under current § 423.2018.

Current § 405.1018(c) addresses new evidence, and is part of the implementation of section 1869(b)(3) of the Act, which precludes a provider or supplier from introducing evidence after the QIC reconsideration unless there is good cause that prevented the evidence from being introduced at or before the QIC's reconsideration. These provisions, which provide for the early submission of evidence, allow adjudicators to obtain evidence necessary to reach the correct decision as early in the appeals process as possible. We are proposing to incorporate current § 405.1018(c), which requires a provider, supplier, or beneficiary represented by a provider or supplier that wishes to introduce new evidence to submit a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker, in proposed § 405.1018(c)(1). However, current § 405.1018 does not address the consequences of not submitting the statement. The statute sets a bar to introducing new evidence, and the submitting party must establish good cause by explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker. However, when a provider or supplier, or beneficiary represented by a provider or supplier, fails to include the required statement, OMHA ALJs and staff spend time seeking out the explanation and following up with parties to fulfill their obligation. Thus, we are proposing to revise § 405.1018(c)(2) to state that if the provider or supplier, or beneficiary represented by a provider or supplier fails to include the statement explaining why the evidence was not previously submitted, the evidence would not be considered. Because only the enrollee is a party to a Part D appeal, there is no corresponding provision in proposed § 423.2016.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Submitting evidence" at the beginning of your comment.

j. Time and Place for a Hearing Before an ALJ (§§ 405.1020 and 423.2020)

As the ALJ hearing function transitioned from SSA, where hearings could be held at over 140 hearing sites nation-wide, to OMHA with four field offices, OMHA became one of the first agencies to use video-teleconferencing (VTC) as the default mode of administrative hearings. The effective use of VTC mitigated OMHA's reduced geographic presence, and allowed OMHA to operate more efficiently and at lower cost to the American taxpayers. However, the preference of most appellants quickly turned to hearings conducted by telephone. In FY 2015, over 98% of hearings before OMHA ALJs were conducted by telephone. Telephone hearings provide parties and their representatives and witnesses with the opportunity to participate in the hearing process with minimal disruption to their day, and require less administrative burden at even lower cost to the American taxpayers than hearings conducted by VTC. OMHA ALJs also prefer telephone hearings in most instances, because they allow more hearings to be conducted without compromising the integrity of the hearing. However, when the ALJ conducting the hearing believes visual interaction is necessary for a hearing, he or she may conduct a VTC hearing, and when special circumstances are presented, ALJs may conduct in-person hearings.

Despite the shift in preferences for most appellants to telephone hearings, current § 405.1020 still makes VTC the default mode of hearing, with the option to offer a telephone hearing to appellants. In fact, some appellants have required the more expensive VTC hearing even when their representative is presenting only argument and no testimony is being offered. We believe this is inefficient and results in wasted time and resources that could be invested in adjudicating additional appeals, and unnecessarily increases the administrative burdens and costs on the government for conducting a hearing with little to no discernable benefit to the parties in adjudicating denials of items or services that have already been furnished. Based on these considerations, we are proposing that a telephone hearing be the default method, unless the appellant is an unrepresented beneficiary. We believe this balances the costs and administrative burdens with the interests of the parties, recognizing that unrepresented beneficiaries may have an increased need and desire to visually interact with the ALJ.

We are proposing in 405.1020(b) to provide two standards for determining how appearances are made, depending on whether appearances are by unrepresented beneficiaries or by individuals other than unrepresented beneficiaries. The provisions of current § 405.1020(b) would be incorporated into proposed § 405.1020(b)(1) and revised to be specific to an appearance by an unrepresented beneficiary who files a request for hearing. We are proposing in subsection (b)(1) that the ALJ would direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by VTC if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance. As in the current rule, we also are proposing in § 405.1020(b)(1) to allow the ALJ to offer to conduct a telephone hearing if the request for hearing or administrative record suggests that a telephone hearing may be more convenient to the unrepresented beneficiary. The current standard for determining whether an in-person hearing should be conducted involves a finding that VTC technology is not available or special or extraordinary circumstances exist. Because, absent special or extraordinary circumstances, a hearing could still be conducted by telephone if VTC technology were unavailable, we are proposing that the standard for an in-person hearing be revised to state that VTC or telephone technology is not available or special or extraordinary circumstances exist, and the determination would be characterized as finding good cause for an in-person hearing, to align with current § 405.1020(i)(5), which provides for granting a request for an in-person hearing on a finding of good cause. We also are proposing in §§ 405.1020(b)(1) and 405.1020(i)(5) to replace the reference to obtaining the concurrence of the "Managing Field Office ALJ" with the "Chief ALJ or designee." The position of the Managing Field Office ALJ became what is now an Associate Chief ALJ, see 80 FR 2708, and using "Chief ALJ or designee" would provide OMHA with the flexibility to designate the appropriate individual regardless of future organizational changes. We are proposing to adopt these revisions in proposed §§ 423.2020(b)(1), for appearances by unrepresented enrollees and 423.2020(i)(5), for when an ALJ may grant a request for an in-person hearing. We are also proposing in § 405.1020(b)(1) to replace "videoteleconferencing," with "video-teleconferencing," for consistency with terminology used in §§ 405.1000, 405.1036, 423.2000, 423.2020 and 423.2036.

Proposed § 405.1020(b)(2) addresses appearances by an individual other than an unrepresented beneficiary who files a request for hearing. We are proposing in § 405.1020(b)(2) that the ALJ would direct that those individuals appear by telephone, unless the ALJ finds good cause for an appearance by other means. Further, we are proposing in § 405.1020(b)(2) that the ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal. Also, we are proposing that the ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if VTC and telephone technology are not available, or special or extraordinary circumstances exist. We are proposing to adopt these revisions in § 423.2020(b)(2) for appearances by represented enrollees, which is more specific than proposed § 405.1020(b)(2) because only enrollees are parties to appeals under part 423, subpart U, and the provisions of subsection (b)(2) would apply only to appearances by represented enrollees.

Current § 405.1020(c)(1) states that the ALJ sends a notice of hearing. This has caused confusion as to whether the ALJ must personally sign the notice, or whether it can be sent at the direction of the ALJ. We believe that the notice may be sent at the direction of the ALJ, and requiring an ALJ signature adds an unnecessary step in the process of issuing the notice. Therefore, we are proposing in § 405.1020(c)(1) that a notice of hearing be sent without further qualification, and to let other provisions indicate the direction that is necessary from the ALJ in order to send the notice, such as § 405.1022(c)(1), which provides that the ALJ sets the time and place of the hearing. We are proposing to adopt these provisions in § 423.2020(a)(1).

Current § 405.1020(c)(1) also requires that the notice of hearing be sent to the parties who filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination, and the QIC that issued the reconsideration. However, there are instances in which a party who does not meet the criteria may face liability because the ALJ may consider a new issue based on a review of the record. To address this, we are proposing in § 405.1020(c)(1) to add that a party that may be found liable based on a review of the record must be sent a notice of hearing. In addition, current § 405.1020 does not address notices of hearing sent to CMS or a non-QIC contractor. Currently, ALJs may also send a notice of hearing to CMS or a contractor when the ALJ believes their input as a participant or party may be beneficial. We are proposing in § 405.1020(c)(1) that the notice of hearing also be sent to CMS or a contractor that the ALJ believes would be beneficial to the hearing. We are not proposing any corresponding revisions to current § 423.2020(c)(1) because only enrollees are parties to appeals under part 423, subpart U.

OMHA ALJs have expressed concern that parties and representatives who appear at a hearing with multiple individuals and witnesses who were not previously identified, complicate and slow the hearing process. While a party or representative has considerable leeway in determining who will attend the hearing or be called as a witness, prior notice of those individuals is necessary for the ALJs to schedule adequate hearing time, manage their dockets, and conduct the hearing. To address these concerns, we are proposing at § 405.1020(c)(2)(ii) to add a requirement to specify the individuals from the entity or organization who plan to attend the hearing if the party or representative is an entity or organization, and at subsection (c)(2)(iii) to add a requirement to list the witnesses who will be providing testimony at the hearing, in the response to the notice of hearing. We also are proposing to consolidate the provisions in current § 405.1020(c)(2)(i) and (c)(2)(ii) in proposed § 405.1020(c)(2)(i) to simplify the provisions related to the current requirements for replying to the notice of hearing. Thus, proposed subsection (c)(2)(i) would require all parties to the ALJ hearing to reply to the notice by acknowledging whether they plan to attend the hearing at the time and place proposed in the hearing, or whether they object to the proposed time and/or place of the hearing. We are proposing at § 423.2020(c)(2) to adopt corresponding revisions for an enrollee's or his or her representative's reply to the notice of hearing.

We also are proposing in § 405.1020(c)(2) to remove the provision for CMS or a contractor that wishes to participate in the hearing to reply to the notice of hearing in the same manner as a party because a non-party may not object to the proposed time and place of the hearing, or present witnesses. Instead, we are proposing in § 405.1020(c)(3) to require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice of hearing by acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing, and specifying who from the entity plans to attend the hearing. We are proposing at § 423.2020(c)(3) to adopt corresponding revisions for CMS', the IRE's, or the Part D plan sponsor' reply to the notice of hearing when the entity requests to attend the hearing as a participant.

In discussing a party's right to waive a hearing, current § 405.1020(d) states that a party may waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record. In light of proposed § 405.1038(b), which would allow attorney adjudicators to issue decisions in appeals that do not require hearings on the record without an ALJ conducting a hearing in certain situations, we are proposing in § 405.1020(d) to state that a party also may waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 405.1038(b), but an ALJ may require the parties to attend a hearing if it is necessary to decide the case. We are proposing at § 423.2020(d) to adopt corresponding revisions for an enrollee to waive his or her right to a hearing and request a decision based on the written evidence in the record in accordance with § 423.2038(b), but an ALJ could require the enrollee to attend a hearing if it is necessary to decide the case. These references would direct readers to the section that provides the authority for a decision based on the written record, which would provide them with a complete explanation of when the authority may be used and notify them that an ALJ or attorney adjudicator may issue the decision.

In addressing the ALJ's authority to change the time or place of the hearing if the party has good cause to object, current § 405.1020(e) requires a party to make the request to change the time or place of the hearing in writing. However, on occasion, a party may need to request a change on the day prior to, or the day of a hearing due to an emergency, such as a sudden illness or injury, or inability to get to a site for the hearing. In this circumstance, we believe an oral request should be permitted. Therefore, we are proposing in § 405.1020(e)(3) that the request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing, and the ALJ must document the oral request in the administrative record. We are proposing at § 423.2020(e)(3) to adopt a corresponding provision for an enrollee to orally request a rescheduled standard hearing, and to modify the documentation requirement, which is currently limited to documenting oral requests made for expedited hearings, to include all oral objections.

In addition, current §§ 405.1020(e)(4) and 423.2020(e)(4), which explain the ALJ may change the time or place of the hearing if the party has good cause, contain a parenthetical that references the procedures that an ALJ follows when a party does not respond to a notice of hearing and fails to appear at the time and place of the hearing. The parenthetical does not appear to address or assist in understanding the circumstances covered by current §§ 405.1020(e)(4) and 423.2020(e)(4), and we, therefore, are proposing to remove the parenthetical from the respective sections.

Current §§ 405.1020(g)(3) and 423.2020(g)(3) provide a list of examples of circumstances a party might give for requesting a change in the time or place of the hearing. We have heard from ALJs and stakeholders that it would be helpful to also include the following two additional examples: (1) The party or representative has a prior commitment that cannot be changed without significant expense, in order to account for circumstances in which travel or other costly events may conflict with the time and place of a hearing, which the ALJ may determines warrants good cause for changing the time or place of the hearing; and (2) the party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place, which the ALJ may determine warrants good cause for changing the time or place of the hearing. We are proposing in §§ 405.1020(g)(3)(vii) and (viii), and 423.1020(g)(3)(vii) and (viii) to add these two examples to address these circumstances. We believe these additional examples would provide greater flexibility in the appeals process and better accommodate the needs of appellants.

We are proposing in §§ 405.1020(h) and 423.2020(h) to revise the references to the adjudication "deadline" with references to the adjudication "period," for consistency in terminology with the specified cross-references.

We are proposing revisions to § 405.1020(i) to align the provision with proposed § 405.1020(b). We are proposing in § 405.1020(i) that if an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or in-person hearing. The party would be required to state the reason for the objection and the time and/or place that he or she wants an in-person or VTC hearing to be held, and the request must be in writing. We are proposing in § 405.1020(i)(4) to incorporate the current § 405.1020(i)(4) provision that requires the appeal to be adjudicated within the time frame specified in § 405.1016 if a request for an in-person or VTC hearing is granted unless the party waives the time frame in writing. However, we are proposing at § 405.1020(i)(4) to revise the language to more accurately state that the ALJ issues a "decision, dismissal, or remand to the QIC," rather than just a "decision," within the adjudication time frame specified in § 405.1016. We are proposing revisions to § 423.2020(i) to align the provision with proposed § 423.2020(b). We are proposing in § 423.2020(i) that if an unrepresented enrollee who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a represented enrollee who filed the request for hearing objects to a telephone or VTC hearing, the enrollee or representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or in-person hearing. The enrollee would be required to state the reason for the objection and the time and/or place that he or she wants an in-person or VTC hearing to be held. We are proposing in § 423.2020(i)(4) to incorporate the current § 423.2020(i)(4) provision with some modifications so that the appeal would be adjudicated within the time frame specified in § 423.2016 if a request for an in-person or VTC hearing is granted unless the party waives the time frame in writing. We are proposing at § 423.2020(i)(4) to revise the language to more accurately state that the ALJ issues a "decision, dismissal, or remand to the IRE," rather than just a "decision," within the adjudication time frame specified in § 405.1016 and to include requests for VTC hearings as well as requests for in-person hearings. In addition, we are proposing at §§ 405.1020(i)(5) and 423.2020(i)(5) to provide that upon a finding of good cause, a hearing would be rescheduled at a time and place when the party may appear in person or by VTC, to account for objections to VTC hearings as well as objections to telephone hearings or offers to conduct a hearing via telephone. We are also proposing to replace "concurrence of the Managing Field Office ALJ" with "concurrence of the Chief ALJ or a designee" because the position of Managing Field Office ALJ was replaced by the position of Associate Chief ALJ (80 FR 2708) and providing a more general reference would provide greater flexibility in the future as position titles change.

Current §§ 405.1020 and 423.2020 do not address what occurs when the ALJ changes the time or place of the hearing. We are proposing at § 405.1020(j) to add a provision titled "Amended notice of hearing" to clarify that, if the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing, in accordance with the procedures of § 405.1022(a), which addresses issuing a notice of hearing. We are proposing at § 423.2020(j) to add a provision to clarify that, if the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with the procedures of § 423.2022(a), which addresses issuing a notice of hearing. These would help ensure that if changes are made to the time or place of the hearing, a new notice is issued or waivers are obtained in a consistent manner.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Time and place for a hearing before an ALJ" at the beginning of your comment.

k. Notice of a Hearing Before an ALJ and Objections to the Issues (§§ 405.1022, 405.1024, 423.2022, and 423.2024)

Current § 405.1022(a) provides that a notice of hearing will be mailed or personally served to the parties and other potential participants, but a notice is not sent to a party who indicates in writing that it does not wish to receive the notice. Current § 423.2022(a) provides that a notice of hearing will be mailed or otherwise transmitted, or personally served, unless the enrollee or other potential participant indicates in writing that he or she does not wish to receive the notice. However, currently § 405.1022(a) is limiting because it does not contemplate transmitting the notice by means other than mail or personal service even though technologies continue to develop and notice could be provided by secure email or a secure portal. Also, notices must be sent in accordance with any OMHA procedures that apply, such as procedures to protect personally identifiable information. In addition, the exception in current § 405.1022(a) does not contemplate a scenario in which a potential participant indicates that it does not wish to receive the notice, as is provided for in current § 423.2022(a). We are proposing in §§ 405.1022(a) and 423.2022(a) to address these issues and align the sections by providing that a notice of hearing would be mailed or otherwise transmitted in accordance with OMHA procedures, or personally served, except to a party or other potential participant who indicates in writing that he or she does not wish to receive the notice.

Current §§ 405.1022(a) and 423.2022(a) provide that a notice of hearing does not have to be sent to a party who indicates in writing that it does not wish to receive the notice and that the notice is mailed or served at least 20 calendar days (for Parts A and B and for non-expedited Part D hearings), or 3 calendar days (for expedited Part D hearings) before the hearing. The provisions do not address the situation where a party wishes to receive the notice, but agrees to the notice being mailed fewer than 20 calendar days (or 3 calendar days if expedited) before the hearing, which may be necessary to accommodate an appellant's request to conduct a hearing in fewer than 20 or 3 calendar days. We are proposing to revise §§ 405.1022(a) and 423.2022(a) to address this situation by providing the notice is mailed, transmitted, or served at least 20 calendar days (or 3 calendar days if expedited) before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days (or 3 calendar days if expedited) before the hearing. However, we note that like a recipient's waiver of receiving a notice of hearing, a recipient's waiver of the requirement to mail, transmit, or serve the notice at least 20 or 3 calendar days (as applicable) before the hearing would only be effective for the waiving recipient and does not affect the rights of other recipients.

Current § 405.1022(b)(1) requires a notice of hearing to contain a statement of the specific issues to be decided and inform the parties that they may designate a person to represent them during the proceedings. These statements of issues take time to develop, and current § 405.1032, which addresses the issues before an ALJ, provides that the issues before the ALJ are all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. Current § 405.1032 also permits an ALJ to consider a new issue at the hearing, if notice of the new issue is provided to all parties before the start of the hearing. To streamline the notice of hearing, rather than require the notice of hearing to contain a statement of the specific issues to be decided, we are proposing in § 405.1022(b)(1) to require the notice of hearing to include a general statement putting the parties on notice that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing. This is consistent with the standard for determining the issues before the ALJ in proposed § 405.1032(a). However, we also are proposing in § 405.1022(b)(1) that the notice of hearing also would contain a statement of any specific new issues that the ALJ will consider in accordance with § 405.1032 to help ensure the parties and potential participants are provided with notice of any new issues of which the ALJ is aware at the time the notice of hearing is sent, and can prepare for the hearing accordingly. For example, if in the request for hearing an appellant raises an issue with the methodology used to sample claims and extrapolate an overpayment, and that issue had not been brought out in the initial determination, redetermination, or reconsideration, the issue would be a new issue and the specific issue would be identified in the notice of hearing. To accommodate proposed § 405.1022(b)(1), we are proposing that the portion of current § 405.1022(b)(1) that requires the notice of hearing to inform the parties that they may designate a person to represent them during the proceedings would be re-designated as § 405.1022(b)(2), and current subsections (b)(2), (b)(3), and (b)(4) would be re-designated as subsections (b)(3), (b)(4), and (b)(5), respectively. We are proposing at § 423.2022(b) to adopt corresponding revisions for notice information in part 423, subpart U proceedings.

Current § 405.1022(c)(1) provides that if the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the party for an explanation. We are proposing to replace "ALJ hearing office" with "OMHA" because OMHA is the responsible entity.

Current § 405.1022(c)(2) provides that if a party states that he or she did not receive the notice of hearing, an amended notice is sent to him or her. The reference to an amended notice has caused confusion, as the original notice does not need to be amended unless the hearing is rescheduled. We are proposing in § 405.1022(c)(2) to remove the reference to an "amended" notice of hearing and provide that a copy of the notice of hearing is sent to the party. However, if a party cannot attend the hearing, we are proposing in new § 405.1022(c)(3) that the party may request that the ALJ reschedule the hearing in accordance with proposed § 405.1020(e), which discusses a party's objection to the time and place of hearing. We are proposing at § 423.2022(c) to adopt corresponding revisions for providing a copy of the notice of hearing if the enrollee did not acknowledge it and states that he or she did not receive it in part 423, subpart U proceedings.

Current § 405.1022(c)(2) provides that if a party did not receive the notice of hearing, a copy of the notice may be sent by certified mail or email, if available. Current § 423.2022(c)(2) provides an additional option to send the copy by fax. However, use of email to send documents that contain a beneficiary's or enrollee's personally identifiable information is not currently permitted by OMHA policy, and faxes must be sent in accordance with procedures to protect personally identifiable information. We are proposing in §§ 405.1022(c)(2) and 423.2022(c)(2) to remove the references to using email and fax, and to add that a notice may be sent by certified mail or other means requested by the party and in accordance with OMHA procedures. This would provide the flexibility to develop alternate means of transmitting the request and allow OMHA to help ensure necessary protections are in place to comply with HHS information security policies. Finally, the parenthetical in current §§ 405.1022(c)(2) and 423.2022(c)(2) is not applicable. We believe it was attempting to cross-reference the provision related to requesting a rescheduled hearing. Therefore, we are proposing in §§ 405.1022(c)(2) and 423.2022(c)(2) to remove the parenthetical. As discussed above, proposed §§ 405.1022(c)(3) and 423.2022(c)(3) would address the option for a party to request a rescheduled hearing and contain the correct cross-reference.

Current § 405.1024 sets forth the provision regarding objections by a party to the issues described in the notice of hearing. Current § 405.1024(b) requires a party to send a copy of its objection to the issues to all other parties to the appeal. We are proposing to revise § 405.1024(b) to provide that the copy is only sent to the parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing, because we believe sending a copy of the objection to additional parties is unnecessary and causes confusion for parties who were not sent a copy of the notice of hearing. No corresponding change is proposed in § 423.2024 because only the enrollee is a party.

Current § 405.1024(c) states that an ALJ makes a decision on the objection to the issues either in writing or at the hearing. We are proposing to revise § 405.1024(c) to add the option for an ALJ to make a decision on the objections at a prehearing conference, which is conducted to facilitate the hearing, as well as at the hearing. We believe this added flexibility would allow ALJs to discuss the objections with the parties and make a decision on the record before the hearing at the prehearing conference. However, we note that the ALJ's decision on an objection to the issues at a prehearing conference pursuant to proposed § 405.1024(c) would not be subject to the objection process for a prehearing conference order under § 405.1040(d). A decision on an objection to the issues is not an agreement or action resulting from the prehearing conference, but rather the ALJ's decision on a procedural matter for which the ALJ has discretion, and we do not believe the parties should have a right of veto through the prehearing conference order objection process. We also are proposing at § 423.2024(c) to adopt a corresponding revision for a decision on an objection to the issues in part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Notice of a hearing before an ALJ and objections to the issue" at the beginning of your comment.

l. Disqualification of the ALJ or Attorney Adjudicator (§§ 405.1026 and 423.2026)

Current § 405.1026 provides a process for a party to request that an ALJ disqualify himself or herself from an appeal, or for an ALJ to disqualify himself or herself from an appeal on the ALJ's own motion. We are proposing to revise § 405.1026 to replace the current references to conducting a hearing with references to adjudicating an appeal, to make it is clear that disqualification is not limited to ALJs or cases where a hearing is conducted to help ensure that an attorney adjudicator, as proposed in section II.B above, also cannot adjudicate an appeal if he or she is prejudiced or partial to any party, or has any interest in the matter pending for decision. Current § 405.1026(b) requires that, if a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing. The ALJ considers the party's objections and decides whether to proceed with the hearing or withdraw. However, the current rule does not address appeals for which no hearing is scheduled and/or no hearing will be conducted. Therefore, we are proposing to revise § 405.1026(b) to require that if a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, or the ALJ or attorney adjudicator any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. We also are proposing to revise § 405.1026(c) to state that an ALJ or attorney adjudicator is "assigned" to adjudicate an appeal, rather than "appointed," for consistency in terminology, and to replace "hearing decision" with "decision or dismissal" because not all decisions are issued following a hearing and an appellant may have objected in an appeal that was dismissed, for which review may also be requested from the Council. In addition, we are proposing to add "if applicable" in discussing that the Council would consider whether a new hearing is held because not all appeals may have had or require a hearing. We are proposing at § 423.2026 to adopt corresponding revisions for disqualification of an ALJ or attorney adjudicator in part 423, subpart U proceedings.

Current § 405.1026 does not address the impact of a party objection and adjudicator's withdrawal on an adjudication time frame. The withdrawal of an adjudicator and re-assignment of an appeal will generally cause a delay in adjudicating the appeal. We are proposing in new § 405.1026(d) that if the party objects to the ALJ or attorney adjudicator, and the ALJ or attorney adjudicator subsequently withdrawals from the appeal, any applicable adjudication time frame that applies is extended by 14 calendar days. This would allow the appeal to be re-assigned and for the new adjudicator to review the appeal. We are proposing at § 423.2026(d) to adopt a corresponding provision for the effect of a disqualification of an adjudicator on an adjudication time frame in part 423, subpart U proceedings, but are proposing that if an expedited hearing is scheduled, the time frame is extended by 2 calendar days, to balance the need for the newly assigned adjudicator to review the appeal, and the enrollee's need to receive a decision as quickly as possible.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Disqualification of the ALJ or attorney adjudicator" at the beginning of your comment.

m. Review of Evidence Submitted by the Parties (§ 405.1028)

Current § 405.1028 addresses the prehearing review of evidence submitted to the ALJ. We are proposing to revise the title of § 405.1028 to reflect that the regulation would more broadly apply to the review of evidence submitted by the parties because a hearing may not be conducted and an attorney adjudicator would review evidence in deciding appeals as proposed in section II.B above.

Proposed § 405.1028(a) would incorporate current § 405.1028(a) to address new evidence. Current § 405.1028(a) states that after a hearing is requested but before it is held, the ALJ will examine any new evidence submitted with the request for hearing (or within 10 calendar days of receiving the notice of hearing) as specified in § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether there was good cause for submitting evidence for the first time at the ALJ level. However, this provision and the other provisions in current § 405.1028 do not address the review of new evidence when no hearing is conducted for an appeal. Therefore, we are proposing to revise § 405.1028(a) to add § 405.1028(a)(1), (2), (3), and (4), and are proposing in § 405.1028(a)(1) that after a hearing is requested but before it is held by an ALJ (to reinforce that hearings are only conducted by ALJs), or a decision is issued if no hearing is held, the ALJ or attorney adjudicator would review any new evidence. In addition, we are proposing in § 405.1028(a)(1) to remove the duplicative statement indicating the review is conducted on "any new evidence submitted with the request for hearing (or within 10 calendar days of receiving the notice of hearing) as specified in § 405.1018," because § 405.1018 discusses when evidence may be submitted prior to a hearing and, as explained in III.A.3.i above, proposed § 405.1018 would revise the language that is duplicated in current § 405.1028. We believe that the better approach going forward is simply to reference § 405.1018 by indicating that the review is conducted on "any new evidence submitted in accordance with § 405.1018." This would remind parties that evidence must be submitted in accordance with § 405.1018, while minimizing confusion on which section is authoritative with regard to when evidence may be submitted.

In a 2012 OIG report on the ALJ hearing process (OEI–02–10–00340), the OIG reported concerns regarding the acceptance of new evidence in light of the statutory limitation at section 1869(b)(3) of the Act on new evidence submitted by providers and suppliers. The OIG concluded that the current regulations regarding the acceptance of new evidence provide little guidance and only one example of good cause, and recommended revising the regulations to provide additional examples and factors for ALJs to consider when determining good cause.

Section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the QIC reconsideration unless there is good cause which precluded the introduction of such evidence at or before that reconsideration. This section presents a Medicare-specific limitation on submitting new evidence, and therefore limits the authority of an ALJ to accept new evidence under the broader APA provisions (see 5 U.S.C. 556(c)(3) ("Subject to published rules of the agency and within its power, employees presiding at hearings may– . . . receive relevant evidence . . . .")). Section 1869(b)(3) of the Act also presents a clear intent by Congress to limit the submission of new evidence after the QIC reconsideration, which must be observed.

In light of the OIG conclusion and recommendation and to more effectively implement section 1869(b)(3) of the Act, we are proposing to incorporate current § 405.1028(b) in proposed § 405.1028(a)(2) on when an ALJ could find good cause for submitting evidence for the first time at the OMHA level, and to establish four additional circumstances in which good cause for submitting new evidence may be found. We are also proposing to permit an attorney adjudicator to find good cause because attorney adjudicators would be examining new evidence in deciding appeals on requests for an ALJ hearing as proposed in section II.B above, and we believe the same standard for considering evidence should apply.

We are proposing in § 405.1028(a)(2)(i) to adopt the example in current § 405.1028(b) and provide that good cause is found when the new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration.

We are proposing in § 405.1028(a)(2)(ii) to provide that good cause is found when the new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with § 405.1032(b). This would provide parties with an opportunity to submit new evidence to address a new issue that was identified after the QIC's reconsideration. However, the authority is limited to ALJs because, as discussed in proposed § 405.1032, only an ALJ may raise a new issue on appeal.

We are proposing in § 405.1028(a)(2)(iii) to provide that good cause is found when the party was unable to obtain the evidence before the QIC issued its reconsideration and the party submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates that the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration. For example, if specific medical records are necessary to support a provider's or supplier's claim for items or services furnished to a beneficiary, the provider or supplier must make reasonable attempts to obtain the medical records, such as requesting records from a beneficiary or the beneficiary's physician when it became clear the records are necessary to support the claim, and following up on the request. Obtaining medical records, in some cases from another health care professional, and submitting those records to support a claim for services furnished to a beneficiary is a basic requirement of the Medicare program (see sections 1815(a) and 1833(e) of the Act, and § 424.5(a)(6)), and we expect instances where records cannot be obtained in the months leading up to a reconsideration should be rare. If the provider or supplier was unable to obtain the records prior to the QIC issuing its reconsideration, good cause for submitting the evidence after the QIC's reconsideration could be found when the ALJ or attorney adjudicator determines that the provider or supplier submitted evidence that demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration.

We are proposing at § 405.1028(a)(2)(iv) to provide that good cause is found when the party asserts that the evidence was submitted to the QIC or another contractor and the party submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates that the new evidence was indeed submitted to the QIC or another contractor before the QIC issued the reconsideration. For example, if a provider or supplier submitted evidence to the QIC or another contractor and through administrative error, the evidence is not associated with the record that is forwarded to OMHA, good cause may be found when the ALJ or attorney adjudicator determines that the provider or supplier submitted evidence that demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration.

Finally, we are proposing at § 405.1028(a)(2)(v) to provide that in circumstances not addressed in proposed paragraphs (i) through (iv), the ALJ or attorney adjudicator may find good cause for new evidence when the ALJ or attorney adjudicator determines the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration. We expect proposed paragraphs (i) through (iv) to cover most circumstances in which a provider or supplier attempts to introduce new evidence after the QIC reconsideration, but we believe this additional provision is necessary to allow for a good cause finding in any other circumstance that meets the requirements of section 1869(b)(3) of the Act. Paragraph (v) helps ensure that OMHA fulfills the statutory requirement by requiring that the ALJ or attorney adjudicator make a determination on whether the party could have obtained the evidence before the QIC issued its reconsideration.

To accommodate the new structure of proposed § 405.1028, we are proposing that current paragraphs (c) and (d) be re-designated as paragraphs (a)(3) and (a)(4), respectively. In addition, we are proposing at § 405.1028(a)(4) that notification about whether the evidence would be considered or excluded applies only when a hearing is conducted, and notification of a determination regarding new evidence would be made only to parties and participants who responded to the notice of hearing, since all parties may not be sent a copy of the notice of hearing or attend the hearing. We note that if a hearing is not conducted, whether the evidence was considered or excluded would be discussed in the decision, pursuant to proposed § 405.1046(a)(1), as discussed in section III.A.3.v below. We also are proposing at § 405.1028(a)(4) that the ALJ would notify all parties and participants whether the new evidence would be considered or is excluded from consideration (rather than only whether the evidence will be excluded from the hearing) and that this determination would be made no later than the start of the hearing, if a hearing is conducted. If evidence is excluded, it is excluded from consideration, not just the hearing, and evidence may be excluded from consideration even when no hearing is conducted. We believe that this would provide greater clarity to parties and participants regarding the ALJ's determination with respect to new evidence, and the effect of the exclusion of such evidence on the proceedings.

Current § 405.1028 does not address duplicative evidence. However, duplicative evidence is a significant challenge for OMHA because appellants often submit copies of medical records and other submissions that were filed at prior levels of appeal and are in the record forwarded to OMHA. While we recognize that appellants want to ensure the evidence is in the record and considered, we are also mindful that the APA provides that as a matter of policy, an agency shall provide for the exclusion of unduly repetitious evidence (see 5 U.S.C. 556(d)).

We are proposing in § 405.1028(b) that the ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA. In addition to establishing a general policy for the exclusion of unduly repetitious evidence, this would reduce confusion as to which of the multiple copies of records to review, and would reduce administrative burden.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Review of evidence submitted by the parties" at the beginning of your comment.

n. ALJ Hearing Procedures (§§ 405.1030 and 423.2030)

The APA provides an ALJ with the authority to regulate the course of a hearing, subject to the rules of the agency (see 5 U.S.C. 556(c)(5)). In rare circumstances, OMHA ALJs have encountered a party or representative that makes it difficult or impossible for the ALJ to regulate the course of a hearing, or for other parties to present their side of the dispute. This may occur when a party or representative continues to present testimony or argument on a matter that is not relevant to the issues before the ALJ, or on a matter for which the ALJ believes he or she has sufficient information or on which the ALJ has already ruled. This may also occur when a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. Sections 405.1030 and 423.2030 sets forth the rules that govern ALJ hearing procedures. We are proposing to revise §§ 405.1030(b) and 423.2030(b) to add provisions to address these circumstances in a consistent manner that protects the interests of the parties and the integrity of the hearing process. To accommodate these proposals, we are proposing to re-designate paragraph (b) in both §§ 405.1030 and 423.2030 as paragraph (b)(1), and to be consistent with proposed §§ 405.1018 and 423.2018, would replace the current language stating that an ALJ may accept "documents that are material to the issues" with "evidence that is material to the issues," because not all evidence that may be submitted is documentary evidence (for example, photographs).

We are proposing in § 405.1030(b)(2) to address circumstances in which a party or representative continues with testimony and argument that are not relevant to the issues before the ALJ or that address a matter for which the ALJ believes he or she has sufficient information or on which the ALJ has already ruled. In these circumstances, the ALJ may limit testimony and/or argument at the hearing, and may, at the ALJ's discretion, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing, within a time frame designated by the ALJ. Proposed § 405.1030(b)(2) would allow the ALJ to effectively regulate the course of the hearing by providing the ALJ with the clear authority to limit testimony and/or argument during the hearing, while providing an avenue for the ALJ to allow the testimony and/or argument to be entered into the record. We are proposing at § 423.2030(b)(2) to adopt a corresponding revision for limiting testimony and argument at a hearing, and at the ALJ's discretion, provide an opportunity to submit additional written statements and affidavits in part 423, subpart U proceedings.

We are proposing at § 405.1030(b)(3) to address circumstances in which a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. In these circumstances, we are proposing that the ALJ would have the clear authority to excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with the opportunity to offer testimony and/or argument. However, in this circumstance, the ALJ would be required to provide the excused party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing. Further, the party also would be allowed to request a copy of the audio recording of the hearing in accordance with § 405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing, within a time frame designated by the ALJ. These proposals would allow the ALJ to effectively regulate the course of the hearing and balance the excused party's right to present his or her case, present rebuttal evidence, and cross-examine the witnesses of other parties with allowing the party to submit written statements and affidavits. We are proposing at § 423.2030(b)(3) to adopt a corresponding revision for excusing an enrollee or representative who is uncooperative, disruptive, or abusive during the hearing in part 423, subpart U proceedings.

Current § 405.1030(c) addresses evidence that the ALJ determines is missing at the hearing, and provides that if the evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine whether the appellant had good cause for not producing the evidence earlier. We are proposing to revise § 405.1030(c) to add that the ALJ must determine whether the appellant had good cause in accordance with § 405.1028 for not producing the evidence. Section 1869(b)(3) of the Act applies to limit submission of all new evidence after the QIC reconsideration by a provider or supplier absent good cause, and the proposed addition would create consistent application of the standards for determining whether there is good cause to admit new evidence, regardless of when the evidence is submitted after the QIC reconsideration. We are not proposing any corresponding changes to current § 423.2030(c) because the limitation on new evidence does not apply in part 423, subpart U proceedings.

Current § 405.1030(d) and (e) discuss what happens if an ALJ determines there was or was not good cause for not producing the new evidence earlier. Current § 405.1030(d) provides that if the ALJ determines that good cause exists, the ALJ considers the evidence in deciding the case, and the adjudication period is tolled from the date of the hearing to the date that the evidence is submitted. Current § 405.1030(e) provides that if the ALJ determines that good cause does not exist, the evidence is excluded, with no impact on an applicable adjudication period. Current § 405.1030(d) and (e) have caused confusion in light of § 405.1018, which indicates that the adjudication period will be affected if evidence is submitted later than 10 calendar days after receipt of the notice of hearing, unless the evidence is submitted by an unrepresented beneficiary. It has also potentially created an incentive for appellants to disregard § 405.1018 because current § 405.1030(b) appears to allow evidence to be submitted at the hearing without affecting the adjudication time frame; and § 405.1030(c) allows the ALJ to stop a hearing temporarily if there is material evidence missing, with the effect of tolling the adjudication time frame from the date of the hearing to the date the evidence is submitted, if the evidence is in the possession of an appellant who is a provider or supplier or beneficiary represented by a provider or supplier, and the ALJ finds good cause to admit the evidence. In addition, OMHA ALJs have expressed concern that current § 405.1030(e) does not affect the adjudication period when an equal amount of time is spent reviewing evidence and making a good cause determination, regardless of whether good cause is found.

Therefore, we are proposing to revise § 405.1030(d) to address the effect of an evidentiary submission on an adjudication period. We are proposing in § 405.1030(d) that any applicable adjudication period is extended in accordance with proposed § 405.1018(b) if an appellant other than an unrepresented beneficiary submits evidence pursuant to proposed § 405.1030(b), which generally allows for submission of evidence at the hearing, or proposed § 405.1030(c), which specifically addresses evidence that the ALJ determines is missing at the hearing. Under proposed § 405.1018(b), any adjudication period that applies to the appeal would be extended by the number of days starting 10 calendar days after receipt of the notice of hearing, and ending when the evidence is submitted, whether it is at the hearing pursuant to proposed § 405.1030(b)(1), or at a later time pursuant to proposed § 405.1030(c). Proposed § 405.1030(d) would provide appellants with an incentive to submit evidence they wish to have considered early in the adjudication process, allow the ALJ to consider the evidence and effectively prepare for the hearing, and minimize any delays in the adjudication process resulting from the late introduction of evidence during the hearing process. Proposed § 405.1030(d) would also remove the potential incentive to disregard § 405.1018, and reconcile any inconsistency in the effect of a late evidentiary submission on an applicable adjudication period by incorporating the § 405.1018 provisions by reference rather than establishing a different standard for evidence submitted during the course of or after a hearing. We are proposing at § 423.2030(d) to adopt a corresponding provision for the effect on an adjudication time frame when new evidence is submitted by a represented enrollee in a standard appeal, or an unrepresented or represented enrollee in an expedited appeal, in accordance with current § 423.2018(b) or (c), as applicable.

Continuing a hearing is referenced in current § 405.1030(c), but is not otherwise addressed in part 405, subpart I. We are proposing in § 405.1030(e)(1) that a hearing may be continued to a later date and that the notice of the continued hearing would be sent in accordance with the proposed § 405.1022, except that a waiver of the notice of hearing may be made in writing or on the record, and the notice of continued hearing would be sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate. The notice requirement would help ensure that the general hearing notice requirements are met for a continued hearing, but allow a waiver of the notice of hearing to be made in writing or on the record. We believe the added option of waiving the notice of hearing on the record in the context of a continued hearing would facilitate scheduling the continued hearing when all parties and participants who are in attendance at the hearing agree to the continued hearing date, or alternatively agree on the record to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing. In addition, proposed § 405.1030(e)(1) would only require that a notice of the continued hearing be sent to the participants and parties who attended the hearing, but would provide the ALJ with the discretion to also send the notice to additional parties, or potential parties or participants. We believe that a notice of the continued hearing to a party, or potential party or participant, who did not attend the hearing is not necessary unless the ALJ determines otherwise based on the circumstances of the case. In the event that the appellant requested the continuance and an adjudication period applies to the appeal, we are proposing in § 405.1030(e)(2) to provide that the adjudication period would be extended by the period between the initial hearing date and the continued hearing date. We believe an appellant's request for a continuance of the hearing is similar to an appellant's request to reschedule a hearing, and if the request is granted, the adjudication period for the appellant's request for hearing should be adjusted accordingly. We are proposing at § 423.2030(e) to adopt corresponding provisions for continued hearings in part 423, subpart U proceedings.

On occasion, after a hearing is conducted, ALJs find that additional testimony or evidence is necessary to decide the issues on appeal, or a procedural matter needs to be addressed. Current § 405.1030(f) allows an ALJ to reopen a hearing to receive new and material evidence pursuant to § 405.986, which requires that the evidence (1) was not available or known at the time of the hearing, and (2) may result in a different conclusion. However, current § 405.1030(f) does not provide a mechanism to address procedural matters, or to obtain additional information through evidence or testimony that may have been available at the time of hearing and may result in a different outcome but the importance of which was not recognized until after a post-hearing review of the case. We are proposing in § 405.1030(f)(1) to remove the "reopen" label and provide for a "supplemental" hearing rather than reopening the hearing to distinguish it from reopening a decision and the standards for reopening a decision. We are also proposing that a supplemental hearing may be conducted at the ALJ's discretion at any time before the ALJ mails a notice of decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ would determine whether a supplemental hearing is necessary, and if one is held, the scope of the supplemental hearing, including when evidence is presented and what issues are discussed. In addition, we are proposing at § 405.1030(f)(1) that a notice of the supplemental hearing be sent in accordance with § 405.1022 to the participants and parties who attended the hearing, but would provide the ALJ with the discretion to also send the notice to additional parties, or potential parties or participants the ALJ determines are appropriate. Similar to the proposed notice of a continued hearing explained above, we believe that a notice of the supplemental hearing to a party, or potential party or participant, who did not attend the hearing is not necessary unless the ALJ determines otherwise based on the circumstances of the case. In the event that the appellant requested the supplemental hearing and an adjudication period applies to the appeal, we are proposing at § 405.1030(f)(2) to provide that the adjudication period would be extended by the period between the initial hearing date and the supplemental hearing date. We believe an appellant's request for a supplemental hearing is similar to an appellant's request for a continuance or to reschedule a hearing, and if the request is granted, the adjudication period for the appellant's request for hearing should be adjusted accordingly. We are proposing at § 423.2030(f) to adopt corresponding provisions for supplemental hearings in part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "ALJ hearing procedures" at the beginning of your comment.

o. Issues Before an ALJ or Attorney Adjudicator (§§ 405.1032 and 423.2032)

Current §§ 405.1032 and 423.2032 address the issues that are before the ALJ. We are proposing to revise the title of the section to indicate that the proposed provision also would apply to issues before an attorney adjudicator, as proposed in section II.B above, if an attorney adjudicator is assigned to an appeal.

Current § 405.1032(a) states that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, when a request for hearing involves a reconsideration of multiple claims and the appellant does not identify one or more of the claims that were not decided entirely in the party's favor at initial determination, redetermination, or reconsideration, it is unclear whether the ALJ should review all of the claims that were not decided entirely in the party's favor at initial determination, redetermination, or reconsideration, or just those claims specified by the appellant in the request for hearing. An appellant is required to identify the dates of service for the claims that it wishes to appeal in its request for hearing under § 405.1014, and some appellants have indicated that they do not specify a denied claim in a request for hearing when they agree that the record does not support coverage of the claim. To address the ambiguity, and in the interest of efficiency and consistency with § 405.1014, we are proposing in § 405.1032(a) that the issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter (for example, for appeals that do not involve a claim for items or services furnished to a beneficiary, such as Medicare Secondary Payer appeals and terminations of coverage) specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. We are proposing at § 423.2032(a) to adopt a corresponding revision for issues in part 423, subpart U proceedings, except the term claims is not used because part 423, subpart U appeals do not involve claims.

Current § 405.1032(a) also notes that if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, the ALJ notifies the parties before the hearing and may consider it an issue at the hearing. As explained in the 2005 Interim Final Rule (70 FR 11462), this provision relates to the favorable portion of an appealed claim, and that the favorable issue is a new issue that must meet the requirements of current paragraph (b). However, in practice, this provision has been read to allow consideration of separate claims that were decided in a party's favor at lower appeal levels in multiple-claim appeals, and at times read independently from paragraph (b). To address this confusion, we are proposing to move this language in § 405.1032(a) to proposed § 405.1032(b), with the revisions discussed below. We are proposing at § 423.2032(a) and (b) to adopt corresponding revisions for new issues in part 423, subpart U proceedings.

Current § 405.1032(b) allows new issues to be considered at the hearing if: (1) the ALJ notifies the parties about the new issue before the start of the hearing; (2) the resolution of the new issue could have a material impact on the claim or claims that are the subject of the request for hearing; and (3) its resolution is permissible under the rules governing reopening of determinations and decisions. We are proposing at § 405.1032(b) to incorporate these provisions, with the revisions discussed below, as well as the language regarding consideration of favorable issues moved from current § 405.1032(a), in a revised structure.

We are proposing in § 405.1032(b)(1) to address when a new issue may be considered. Specifically, we are proposing that the ALJ may only consider the new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or appealed matter, and (1) there is new or material evidence that was not available or known at the time of the determination and which may result in a different conclusion, or (2) the evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination. This would consolidate the current provisions to better convey when a new issue may be considered, clarify that a new issue relates to a claim or appealed matter specified in the request for hearing, and provide the applicable standards from the reopening rules referenced in current § 405.1032(b)(1)(ii). We are proposing in § 405.1032(b)(1) to continue to provide that the new issue may be raised by the ALJ or any party and may include issues resulting from the participation of CMS, but correct the language so that it also references participation of CMS contractors. We are proposing at § 423.2032(b)(1) to adopt corresponding revisions for when new issues may be considered in part 423, subpart U proceedings.

We are proposing at § 405.1032(b)(2) to continue to provide that notice of the new issue must be provided before the start of the hearing, but would limit the notice to the parties who were or will be sent the notice of hearing, rather than the current standard to notice "all of the parties." Because notice of the new issue may be made in the notice of hearing or after the notice of hearing, and parties generally have 10 calendar days after receipt of the notice of hearing to submit evidence, we are proposing at § 405.1032(b)(3) to also provide that if notice of the new issue is sent after the notice of hearing, the parties would have at least 10 calendar days after receiving the notice of the new issue to submit evidence regarding the issue. As provided in proposed § 405.1028(a)(2)(ii), the ALJ would then determine whether the new evidence is material to the new issue identified by the ALJ. If an adjudication time frame applies to the appeal, the adjudication period would not be affected by the submission of evidence. Further, we are proposing at § 405.1032(b)(3) that if the hearing is conducted before the time to submit evidence regarding the issue expires, the record would remain open until the opportunity to submit evidence expires to provide the parties sufficient time to submit evidence regarding the issue. We are proposing at § 423.2032(b)(2) and (b)(3) to adopt corresponding provisions for providing notice of new issues to enrollees and an opportunity to submit evidence, and to add that an enrollee will have 2 calendar days after receiving notice of the new issue in an expedited appeal to submit evidence, which corresponds to the length of time permitted under proposed § 423.2018(c) to submit evidence after receiving a notice of expedited hearing.

Current § 405.1032(c) states that an ALJ cannot add any claim, including one that is related to an issue that is appropriately before an ALJ, to a pending appeal unless the claim has been adjudicated at the lower appeal levels and all parties are notified of the new issues before the start of the hearing. However, in practice, we are unaware that this provision is used, and to the extent it may be used, we believe it would be disruptive to the adjudication process, result in filing requirements not being observed, and risk adjudication of the same claim by multiple adjudicators. Therefore, we are proposing to maintain the topic of adding claims to a pending appeal, but replace the language of current § 405.1032(c), as explained below.

A reconsideration may be appealed for an ALJ hearing regardless of the number of claims involved in the reconsideration. However, we recognize that a party may not specify all of the claims from a reconsideration that he or she wishes to appeal in the party's request for hearing. We are proposing in § 405.1032(c)(1) to address this circumstance by providing that claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed in the request for hearing, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims to be added in accordance with proposed § 405.1014(e). We believe that this would result in less disruption to the adjudication process, greater adherence to filing requirements, and reduce the risk of adjudication of the same claim by multiple adjudicators. To help ensure that the copy requirement of proposed § 405.1014(d) is observed, we are proposing at § 405.1032(c)(2) to require that before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates that the information that constitutes a complete request for hearing in accordance with § 405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with § 405.1014(d). We are proposing at § 423.2032(c) to adopt a provision corresponding to proposed § 405.1032(c)(1), but we are not proposing to adopt a provision corresponding to § 405.1032(c)(2) because there is no § 423.2014 requirement for an enrollee to send a copy of his or her request to others.

Current § 405.1032 does not address issues related to an appeal that involves a disagreement with how a statistical sample and/or extrapolation was conducted. When an appeal involves a statistical sample and an extrapolation and the appellant wishes to challenge how the statistical sample and/or extrapolation was conducted, as discussed previously, we are proposing at § 405.1014(a)(3)(iii) to require the appellant to assert the reasons the appellant disagrees with how the statistical sampling and/or extrapolation was conducted in the request for hearing. We are proposing at § 405.1032(d)(1) to reinforce this requirement by excluding issues related to how the statistical sample and/or extrapolation were conducted if the appellant does not comply with § 405.1014(a)(3)(iii). In addition to reinforcing the proposed requirement at § 405.1014(a)(3)(iii), we believe that excluding the issue is appropriate because an appellant should reasonably be aware of whether it disagrees with how the statistical sampling and/or extrapolation was conducted at the time it files a request for hearing, and raising the issue later in the adjudication process or at the hearing can cause significant delays in adjudicating an appeal because the ALJ may need to conduct additional fact finding, find it necessary to request participation of CMS or one of its contractors, and/or call expert witnesses to help address the issue.

Related to the issues that an ALJ must consider, the 2005 Interim Final Rule (70 FR 11466) explained that current § 405.1064 was added to set forth a general rule regarding ALJ decisions that are based on statistical samples because a decision that is based on only a portion of a statistical sample does not accurately reflect the entire record. As discussed in the 2009 Final Rule (74 FR 65328), current § 405.1064 explains that when an appeal from the QIC involves an overpayment, and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of all claims in the sample. However, while a review of the claims selected for the sample is necessary to review issues related to a contested sample and extrapolation, for example to determine whether the sample claims were appropriately selected for a representative sample of the universe, current § 405.1064 has been read more broadly to also require adjudication of each sample claim, regardless of whether the sample claim was adjudicated favorably at lower appeal levels. We do not believe adjudicating sample claims that were decided favorably at lower levels of appeal, or sample claims that are not appealed by a party, is necessary to adjudicate broader issues with how sampling and extrapolation was conducted, and the broader reading of current § 405.1064 results in unnecessary adjudications of claims that were not appealed.

To clarify what is at issue and what must be considered in appeals involving statistical sampling and extrapolations, we are proposing to remove current § 405.1064, and address the matter in § 405.1032(d)(2). We are proposing in § 405.1032(d)(2) that if a party asserts a disagreement with how the statistical sampling methodology and extrapolation were conducted in the request for hearing, in accordance with proposed § 405.1014(a)(3)(iii), § 405.1032(a) through (c) would apply to the adjudication of the sample claims. The result of applying proposed § 405.1032(a) and (b) would be that only the sample units that were specified in the request for hearing are individually adjudicated, subject to a new issue being identified for an appealed claim. However, proposed § 405.1032(c) would permit adding sample claims to a pending appeal if they were adjudicated in the appealed reconsideration and the time to request a hearing on the reconsideration has not expired, or the ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims in accordance with § 405.1014(e). To incorporate the principle embodied in current § 405.1064, we are proposing in § 405.1032(d)(2) that in deciding issues related to how a statistical sample and/or extrapolation was conducted, the ALJ or attorney adjudicator would base his or her decision on a review of the entire sample to the extent appropriate to decide the issue. We believe this more clearly conveys the intent of the rule and recognizes that an individual adjudication of each claim in the sample is not always necessary to decide an issue related to how a statistical sample and/or extrapolation was conducted, such as whether there is documentation so that the sampling frame can be re-created, as required by the Medicare Program Integrity Manual (Internet-Only Manual 100–08) (see chapter 8, § 8.4.4.4.1). We are not proposing any corresponding changes in § 423.2030 because statistical sampling and extrapolation are not currently used for matters that are subject to part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Issues before an ALJ or attorney adjudicator" at the beginning of your comment.

p. Requesting Information From the QIC or IRE, and Remanding an Appeal (§§ 405.1034, 405.1056, 405.1058, 423.2034, 423.2056, and 423.2058)

Current §§ 405.1034 and 423.2034 describe when an ALJ may request information from, or remand a case to a QIC or IRE. When the ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, including an IRE, or the Part D plan sponsor, current §§ 405.1034(a) and 423.2034(a) allow an ALJ to remand the case to the QIC or IRE that issued the reconsideration, or retain jurisdiction of the case and request that the entity forward the missing information to the appropriate hearing office. The 2005 Interim Final Rule (70 FR 11465) explained that in the rare instance in which the file lacks necessary technical information that can only be provided by CMS or its contractors, it was believed that the most effective way of completing the record is to return the case, via remand, to the contractor; however, the ALJ also had the option of asking the entity to forward the missing information to the ALJ hearing office. In practice, stakeholders have expressed frustration and concern with the remand provisions because in accordance with the definition of a remand in § 405.902, a remand vacates the lower level appeal decision and therefore may require a QIC or IRE to issue a new reconsideration, for which the appellant must submit a new request for hearing, which causes additional delay in reaching finality on the disputed claims. In addition, current §§ 405.1034 and 423.2034 do not address providing notice of a remand or the effects of a remand.

To address stakeholders' concerns with the current remand provisions, and areas not addressed in current §§ 405.1034 and 423.2034, we are proposing to revise the sections to cover obtaining information that can be provided only by CMS or its contractors, or the Part D plan sponsor, and establishing new §§ 405.1056 and 405.1058 to address remands to a QIC, and new §§ 423.2056 and 423.2058 to address remands to an IRE.

We are proposing in § 405.1034(a) to maintain the current standards for requesting information that is missing from the written record when that information can be provided only by CMS or its contractors, but limit the action to a request for information directed to the QIC that conducted the reconsideration or its successor (if a QIC contract has been awarded to a new contractor). In addition, we are revising § 405.1034(a) to include attorney adjudicators because attorney adjudicators would be authorized to adjudicate appeals, as proposed in section II.B. Also, while we are proposing to retain the definition of "can be provided only by CMS or its contractors" in § 405.1034(a)(2), we are proposing at § 405.1034(a)(1) to specify that official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors. The redetermination and reconsideration are important documents that establish the issues on appeal, and while the parties often have copies of them, we believe the record should include official copies from the contractors. In addition, we are proposing at § 405.1034(b) to specify that the ALJ or attorney adjudicator would retain jurisdiction of the case, and the case would remain pending at OMHA. We are proposing at § 423.2034(a) and (b) to adopt corresponding provisions for when information may be requested from an IRE and that jurisdiction is retained at OMHA in part 423, subpart U proceedings.

We are proposing in § 405.1034(c) that the QIC would have 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the request for information, either directly or through CMS or another contractor. This proposal would provide the ALJ or attorney adjudicator, the QIC, and the parties with a benchmark for obtaining the information and determining when adjudication of the case can resume. We are proposing in § 405.1034(d) that, if an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period would be extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever is less. We recognize that other provisions that extend an applicable adjudication period generally involve an appellant's action or omission that delays adjudicating an appeal within an applicable time frame, but we believe that an extension is also warranted to fully develop the record when the written record is missing information that is essential to resolving the issues on appeal, and that 20 calendar days (5 calendar days for the request to be received by the QIC and 15 calendar days for the QIC to respond) is a relatively modest delay in order to obtain missing information that is essential to resolving the appeal. We are proposing at § 423.2034(c) and (d) to adopt corresponding provisions for the IRE to furnish the information or otherwise respond to the request for information, either directly or through CMS or the Part D plan sponsor, and the effect on any applicable adjudication time frame in part 423, subpart U proceedings. In addition, we are proposing at § 423.2034(c) and (d) to provide for an accelerated response time frame for expedited appeals because of the urgency involved. For expedited appeals, we are proposing that the IRE would have 2 calendar days after receiving a request for information to furnish the information or otherwise respond to the request, and the extension to the adjudication time frame would be up to 3 calendar days, to allow for time to transmit the request to the IRE and for the IRE to respond.

We are proposing to add new § 405.1056 to describe when a request for hearing or request for review of a QIC dismissal may be remanded, and new § 405.1058 to describe the effect of a remand. We are proposing in § 405.1056(a)(1) to permit a remand if an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with proposed § 405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in § 405.1034. We also are proposing in § 405.1056(a)(2) to permit a remand when the QIC does not furnish a case file for an appealed reconsideration. The remand under both provisions would direct the QIC or other contractor (such as a Medicare Administrative Contractor that made the redetermination) to reconstruct the record or initiate a new appeal adjudication. We expect this type of remand to be very rare, but we believe it is necessary to help ensure a complete administrative record of the administrative adjudication of a claim. To address the possibility that the QIC or another contractor is able to reconstruct the record for a remanded case, we are proposing in § 405.1056(a)(3) to provide that in the situation where a record is reconstructed by the QIC, the reconstructed record would be returned to OMHA, the case would no longer be remanded and the reconsideration would no longer be vacated, and if an adjudication period applies to the case, the period would be extended by the time between the date of the remand and the date the case is returned to OMHA because OMHA was unable to adjudicate the appeal between when it was remanded and when it was returned to OMHA. This would help ensure that appellants are not required to re-start the ALJ hearing or dismissal review process in the event that the QIC or another contractor is able to reconstruct the record. We are proposing at § 423.2056(a) to adopt corresponding provisions for remanding cases in which there is a missing appeal determination or the IRE is unable to furnish the case file in part 423, subpart U proceedings.

On occasion, an ALJ finds that a QIC issued a reconsideration that addresses coverage or payment issues related to the appealed claim when a redetermination was required and no redetermination was conducted, or the contractor dismissed the request for redetermination and the appellant appealed the contractor's dismissal. In either circumstance, the reconsideration was issued in error because the appellant did not have a right to the reconsideration in accordance with current § 405.960, which only provides a right to a reconsideration when a redetermination is made by a contractor. We do not believe that an administrative error made by the QIC conveys rights that are not afforded under the rules. We are proposing in § 405.1056(b) to address these circumstances so that, if an ALJ or attorney adjudicator finds that the QIC issued a reconsideration that addressed coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required) or the request for redetermination was dismissed (and not vacated), the reconsideration would be remanded to the QIC that issued the reconsideration, or its successor, to re-adjudicate the request for reconsideration. We again expect this type of remand to be rare, but believe it is necessary to correct administrative errors in the adjudication process. We are proposing at § 423.2056(b) to adopt a corresponding provision for when an IRE issues a reconsideration that addresses drug coverage when no redetermination was conducted or a request for redetermination was dismissed and is appealed to OMHA under part 423, subpart U.

OMHA ALJs sometimes receive requests for remands from CMS or a party because the matter can be resolved by a CMS contractor if jurisdiction of the claim is returned to the QIC. Current § 405.1034 does not address this type of request. We are proposing at § 405.1056(c)(1) to provide a mechanism for these remands. Specifically, we are proposing that at any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors, may jointly request a remand of the appeal to the entity that conducted the reconsideration. We are proposing that the request include the reasons why the appeal should be remanded and indicate whether remanding the case would likely resolve the matter in dispute. Proposed § 405.1056(c)(2) would allow the ALJ or attorney adjudicator to determine whether to grant the request and issue the remand, based on his or her determination of whether remanding the case would likely resolve the matter in dispute. We believe this added flexibility would allow appellants and CMS and its contractors to expedite resolution of a disputed claim when there is agreement to do so. We are proposing at § 423.2056(c) to adopt corresponding provisions for requested remands in part 423, subpart U proceedings.

Current § 405.1034(b) provides that if, consistent with current § 405.1004(b), the ALJ determines that a QIC's dismissal of a request for reconsideration was in error, the case will be remanded to the QIC. We are proposing at § 405.1056(d) to incorporate this provision and proposed § 423.2056(d) would adopt a corresponding provision to incorporate current § 423.2034(b)(1) for remanding cases in which an IRE's dismissal of a request for reconsideration was in error, in part 423, subpart U proceedings. In addition, we are proposing at § 423.2056(e) to incorporate current § 423.2034(b)(2), which provides that if an enrollee wants evidence of a change in his or her condition to be considered in the appeal, the appeal would be remanded to the IRE for consideration of the evidence on the change in condition.

Current § 405.1034(c) provides that the ALJ remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1), and provides that unless the appellant is entitled to such relief, the ALJ applies the LCD or NCD in place on the date the item or service was provided. We are proposing to incorporate these provisions at § 405.1056(e). We did not propose any corresponding provision for § 423.2056 because there is not a similar current provision for part 423, subpart U proceedings.

As noted above, current § 405.1034 does not address providing a notice of remand. We are proposing at § 405.1056(f) to provide that OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant to the proceedings or a party to the hearing. The notice would state that, as discussed below, there is a right to request that the Chief ALJ or a designee review the remand. We believe this would help ensure that the parties and CMS and its contractors receive notice that the remand order has been issued. We are proposing at § 423.2056(f) to adopt a corresponding provision for a notice of remand in part

423, subpart U proceedings, except that only the enrollee receives notice because only the enrollee is a party, and CMS, the IRE, and the Part D plan sponsor only receive notice if they requested to participate and the request was granted.

Stakeholders have recounted instances in which they believe a remand was not authorized by the regulations, but were unable to take any action to correct the perceived error because a remand is not an appealable action and current § 405.1034 does not provide a review mechanism. We do not believe that remands should be made appealable actions, but recognize that stakeholders need a mechanism to address remands that they believe are not authorized by the regulation. We are proposing in § 405.1056(g) to provide a mechanism to request a review of a remand by allowing a party or CMS, or one of its contractors, to file a request to review a remand with the Chief ALJ or a designee within 30 calendar days of receiving a notice of remand. If the Chief ALJ or designee determines that the remand is not authorized by § 405.1056, the remand order would be vacated. We are also proposing that the determination on a request to review a remand order is binding and not subject to further review so adjudication of the appeal can proceed. We are proposing at § 423.2056(g) to adopt a corresponding provision for reviewing a remand in part 423, subpart U proceedings.

Current § 405.1034 does not discuss the effect of a remand. We are proposing at § 405.1058, similar to current §§ 405.1048 and 405.1054 which describe the effects of a decision and dismissal, respectively, that a remand of a request for hearing or request for review is binding unless it is vacated by the Chief ALJ or a designee in accordance with proposed § 405.1056(g). We believe the provision would add clarity for the parties and other stakeholders on the effect of a remand order. We are proposing at § 423.2058 to adopt a corresponding provision for the effect of a remand in part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Requesting information from the QIC or IRE, and remanding an appeal" at the beginning of your comment.

q. Description of the ALJ Hearing Process and Discovery (§§ 405.1036, 405.1037, and 423.2036)

Current §§ 405.1036 and 423.2036 describe the ALJ hearing process, including the right to appear and present evidence, waiving the right to appear at the hearing, presenting written statements and oral arguments, waiver of the adjudication period, what evidence is admissible at the hearing, subpoenas, and witnesses at a hearing. Current § 405.1037 describes the discovery process in part 405, subpart I proceedings, which is permitted when CMS or a contractor elects to be a party to the ALJ hearing; there is no corresponding provision for part 423, subpart U proceedings because CMS, the IRE, and the Part D plan sponsor may not be made parties to the hearing.

Current § 405.1036(b)(1) states that a party may "send the ALJ" a written statement indicating that he or she does not wish to appear at the hearing. We are proposing at § 405.1036(b)(1) to revise this provision to state that a party may "submit to OMHA" a written statement indicating that he or she does not wish to appear at the hearing. While the written statement could still be sent to an ALJ who is assigned to a request for hearing, we are proposing that the statement could be submitted to OMHA (for example, the statement could be submitted with the request for hearing), or to the ALJ or attorney adjudicator, as proposed in section II.B above, after the request is assigned, to provide more flexibility and to accommodate situations where an ALJ or attorney adjudicator has not been assigned a request for hearing. We are proposing at § 423.2036(b)(1) to adopt a corresponding revision for submitting a waiver of the right to appear in part 423, subpart U proceedings. In addition, we are proposing at § 423.2036(b)(1)(ii) to revise the current requirement for the "ALJ hearing office" to document oral requests to require "OMHA" to document oral requests, to help ensure that applicability of the requirement is clear regardless of whether the oral request is received by an adjudicator in an OMHA field office after the appeal is assigned to an ALJ or attorney adjudicator, or the oral request is received in the OMHA central office before the appeal is assigned to an ALJ or attorney adjudicator.

As discussed in section III.A.3.h above, we are proposing to move the provision for waiving the adjudication period from current § 405.1036(d) to proposed § 405.1016(d) because proposed § 405.1016 addresses adjudication time frames and we believe the section is a better place for discussing adjudication time frame waivers. To accommodate moving current § 405.1036(d) to proposed § 405.1016(d), we are proposing to re-designate current § 405.1036(g), which describes witnesses at the hearing, as proposed § 405.1036(d) because it more logically follows the discussion of presenting witnesses and oral arguments in current § 405.1036(c). For the same reasons, we are proposing to move the provisions at § 423.2036(d) to proposed § 423.2016(c), and proposing at § 423.2036(d) to re-designate current § 423.2036(g) as proposed § 423.2036(d) to describe witnesses at a hearing in part 423, subpart U proceedings.

Current § 405.1036(f) discusses subpoenas. Current § 405.1036(f)(5)(i) states that an ALJ ruling on a subpoena request is not subject to immediate review by the Council and may be reviewed solely during the course of the Council's review specified in § 405.1102 (for requests for Council review when an ALJ issues a decision or dismissal), § 405.1104 (for requests for escalation to the Council), or § 405.1110 (for referrals for own motion review by the Council). As discussed in section III.A.3.h.ii above, we are proposing to remove section § 405.1104 and relocate provisions dealing with escalation to the Council to § 405.1016. Because the process for requesting escalation to the Council is now described in proposed § 405.1016(e) and (f), we are proposing at § 405.1036(f)(5)(i) to replace the reference to § 405.1104 with a reference to § 405.1016(e) and (f). Current § 405.1036(f)(5)(ii) discusses CMS objections to a "discovery ruling" in the context of a paragraph on reviewability of subpoena rulings and current § 405.1037(e)(2)(i) separately addresses CMS objections to a discovery ruling. We are proposing to revise § 405.1036(f)(5)(ii) to replace the current reference to a "discovery ruling" with "subpoena ruling" so it is consistent with the topic covered by § 405.1036(f). No corresponding revisions are necessary in § 423.2036(f) because there is no reference to a "discovery ruling."

Current § 405.1037(a)(1) provides that discovery is permissible only when CMS or its contractors elects to participate in an ALJ hearing as a party. While the intent is generally clear, the use of "participate" is potentially confusing given CMS or one of its contractors can elect to be a participant in the proceedings, including the hearing, in accordance with current and proposed § 405.1010, or elect to be a party to the hearing in accordance with current and proposed § 405.1012. We are proposing to revise § 405.1037(a)(1) to state that discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with proposed § 405.1012. As noted above, there are no provisions for discovery in part 423, subpart U proceedings because CMS, the IRE, or the Part D plan sponsor are not permitted to be a party to the hearing.

Current § 405.1037(e)(1) states that an ALJ discovery ruling or disclosure ruling is not subject to immediate review by the Council and may be reviewed solely during the course of the Council's review specified in § 405.1100 (for Council review in general), § 405.1102 (for requests for Council review when an ALJ issues a decision or dismissal), § 405.1104 (for requests for escalation to the Council), or § 405.1110 (for referrals for own motion review by the Council). For the reasons discussed above with regard to similar proposed changes in § 405.1036, we are proposing at § 405.1037(e)(1) to replace the reference to § 405.1104 with a reference to § 405.1016(e) and (f).

Current § 405.1037(f) describes the effect of discovery on an adjudication time frame, and provides that the time frame is tolled until the discovery dispute is resolved. However, it does not clearly state when the effect on an adjudication time frame begins, and "discovery dispute" is not used elsewhere in the section. In addition, current § 405.1037(f) does not contemplate that an adjudication time frame may not apply (for example, when the adjudication time frame is waived in accordance with proposed § 405.1016(d)). Therefore, we are proposing to revise § 405.1037(f) to state that if an adjudication period applies to the appeal in accordance with § 405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery. We believe this revision would provide a clearer standard for how an adjudication period is affected by discovery proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Description of the ALJ hearing process and discovery" at the beginning of your comment.

r. Deciding a Case Without a Hearing Before an ALJ (§§ 405.1038 and 423.2038)

Current § 405.1038(a) provides authority to issue a "wholly favorable" decision without a hearing before an ALJ and without giving the parties prior notice when the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue. We are proposing in § 405.1038 that if the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator, as proposed in section II.B above, may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012. Proposed § 405.1038(a) would replace "wholly favorable" with "fully favorable" in the subsection heading to align with language in § 405.1000(g), which addresses a fully favorable decision being made on the record, and the nomenclature used in OMHA's day to day operations. Proposed § 405.1038(a) would also replace "hearing record" with "administrative record" for consistency with other references to the record, and replace "hearing decision" with "decision," for consistency with other references to a decision. We are proposing at § 423.2038(a) to adopt corresponding revisions to align with language in § 423.2000(g) and to make references to the record and decisions consistent in part 423, subpart U proceedings.

Proposed § 405.1038(a) would also add two new limitations on issuing a decision without a hearing before an ALJ when the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue. First, a decision could not be issued pursuant to proposed § 405.1038(a) if another party to the appeal is liable for the claims at issue. Second, a decision could not be issued pursuant to proposed § 405.1038(a) if CMS or a contractor elected to be a party to the hearing in accordance with § 405.1012. We recognize that this may limit decisions that may be issued pursuant to § 405.1038(a); however, we believe only a small number of appeals would be affected, and the new limitations would mitigate the impact of such a decision on the other parties to the appeal and the likelihood of an appeal to, and remand from, the Council. No corresponding changes are proposed in § 423.2038(a) because only the enrollee is a party in part 423, subpart U proceedings.

Current § 405.1038(b)(1) permits the ALJ to decide a case on the record and not conduct a hearing if: (1) All the parties indicate in writing that they do not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or (2) an appellant lives outside of the United States and does not inform the ALJ that he or she wants to appear, and there are no other parties who wish to appear. We are proposing to retain this structure in proposed § 405.1038(b) but are proposing some changes. Current § 405.1038(b)(1)(i) requires all parties to indicate in writing that they do not wish to appear before the ALJ at a hearing, and as indicated above, current § 405.1038(b)(1)(ii) is contingent on no other parties wishing to appeal. However, the requirement to obtain a writing from all parties or determine the wishes of the non-appellant parties has limited the utility of the provisions. While all parties have a right to appear at the hearing, a notice of hearing is not sent to parties who did not participate in the reconsideration and were not found liable for the items or services at issue after the initial determination, in accordance with current § 405.1020(c). We are proposing at § 405.1038(b)(1)(i) and (b)(1)(ii) to modify the requirements so writings only need to be obtained from, or wishes assessed from, parties who would be sent a notice of hearing, if a hearing were to be conducted. Using the notice of hearing standard protects the interests of potentially liable parties, while making the provisions a more effective option for the efficient adjudication of appeals. In addition, proposed § 405.1038(b)(1) would reinforce that only an ALJ conducts a hearing by indicating an ALJ or attorney adjudicator may decide a case on the record without an ALJ conducting a hearing. Proposed § 405.1038(b)(1)(ii) also would indicate that an appellant who lives outside of the United States would inform "OMHA" rather than "the ALJ" that he or she wants to appear at a hearing before an ALJ, so an appellant could make that indication before an appeal is assigned to an ALJ or attorney adjudicator. We are proposing at § 423.2038(b)(1) and (b)(1)(ii) to adopt corresponding revisions to reinforce that only an ALJ conducts a hearing and an enrollee who lives outside of the United States would inform OMHA that he or she wishes to appear at a hearing before an ALJ, but the other changes in proposed § 405.1038(b) are not made to § 423.2038(b) because only the enrollee is a party in part 423, subpart U proceedings. We are also proposing in § 405.1038(b)(1)(i) to replace "videoteleconferencing," and in § 423.2038(b)(1)(i) to replace "video teleconferencing," with "video-teleconferencing," for consistency with terminology used in §§ 405.1000, 405.1036, 423.2000, 423.2020, and 423.2036.

On occasion, CMS or one of its contractors indicates that it believes an item or service should be covered or payment made on an appealed claim, either before or at a hearing. However, there are no current provisions that address this circumstance and it is one that is ideal for a summary decision in favor of the parties based on the statement by CMS or its contractor, in lieu of a full decision that includes findings of fact, conclusions of law, and other decision requirements. We are proposing to add § 405.1038(c) to provide a new authority for a stipulated decision, when CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or paid. In this situation, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision. We are proposing at § 423.2038(c) to adopt a corresponding authority for stipulated decisions in part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Deciding a case without a hearing before an ALJ" at the beginning of your comment.

s. Prehearing and Posthearing Conferences (§§ 405.1040 and 423.2040)

Current § 405.1040 discusses prehearing and posthearing conferences and permits the ALJ to hold these conferences to facilitate the hearing or hearing decision. Current § 405.1040(b) requires an ALJ to inform "the parties" of the time, place, and purpose of the prehearing or posthearing conference, unless a party indicates in writing that it does not wish to receive a written notice of the conference. In accordance with current § 405.1020(c), the notice of hearing is not sent to a party who did not participate in the reconsideration and was not found liable for the services at issue after the initial determination. Therefore, we are proposing to modify § 405.1040(b) to state that the ALJ would inform parties who would be or were sent a notice of hearing in accordance with § 405.1020(c). In addition, current § 405.1040(b) does not provide for conference notice to be sent to CMS or a contractor that elected to be a participant in the proceedings or a party to the hearing at the time the conference notice is sent, which has caused confusion when CMS or a contractor has made an election before or after a conference. Therefore, we are proposing at § 405.1040(b) that a conference notice be sent to CMS or a contractor that has elected to be a participant in the proceedings or a party to the hearing at the time the conference notice is sent. We believe these changes would help ensure the appropriate parties and participants are provided with notice of, and have an opportunity to attend, a conference. We are proposing at § 423.2040(b) and (c) to adopt corresponding revisions for prehearing conference notices in non-expedited and expedited hearings respectively to state that a conference notice is sent to CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant in the hearing, but we are not proposing to make other changes in proposed § 405.1040(b) to § 423.2040 because only the enrollee is a party in part 423, subpart U proceedings. In addition, because an oral request not to receive a notice of the conference is permitted for expedited hearings, we are proposing at § 423.2040(d) to revise the requirement for an "ALJ hearing office" to document such an oral request to provide more generally that oral requests must be documented, which is generally done by the ALJ's support staff, rather than other office staff. In addition, we are proposing at § 423.2040(d) that documentation of an oral request not to receive written notice of the conference must be added to the administrative record for consistency in how the record is referenced.

Current § 405.1040(c) states that, at the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the parties consent in writing. However, OMHA ALJs have indicated that providing them with the discretion to delegate conducting a conference to an attorney would add efficiency to the process. OMHA attorneys are licensed attorneys who support ALJs in evaluating appeals and preparing appeals for hearing, as well as drafting decisions, and are well versed in Medicare coverage and payment policy, as well as administrative procedure. Therefore, we are proposing at § 405.1040(c)(1) that, at the conference, the ALJ or an OMHA attorney designated by the ALJ may conduct the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice if the parties consent to consideration of the additional matters in writing. This revision would allow an OMHA attorney designated by the ALJ assigned to an appeal to conduct a conference, but would only allow an ALJ conducting the conference to consider matters in addition to those stated in the conference notice. We believe allowing ALJs to delegate the task of conducting a conference (consistent with the conference notice stating the purpose of the conference, in accordance with § 405.1040(b)) would provide ALJs with the flexibility to use OMHA attorneys and provide ALJs with more time to devote to hearings and decisions. We also believe using attorneys to conduct conferences is appropriate because conferences are informal proceedings to facilitate a hearing or decision, and do not involve taking testimony or receiving evidence, both of which occur at the hearing. We also note that the results of the conference embodied in a conference order are subject to review and approval by the ALJ, and ultimately subject to an objection by the parties, under the provisions of current § 405.1040, which are carried over in proposed § 405.1040. We are proposing at § 423.2040(e)(1) to adopt corresponding revisions for allowing an ALJ to delegate conducting a conference to an OMHA attorney, in part 423, subpart U proceedings.

Current § 405.1040(c) references the notice of hearing in discussing the matters that are considered at a conference. However, a notice of hearing may not have been issued at the time a prehearing conference is scheduled, and the matters being addressed in the appeal may have evolved since a notice of hearing was issued by the time a posthearing conference is scheduled, resulting in confusion on the permissible scope of the matters discussed at a conference. Therefore, § 405.1040(c)(1) would state that the matters that are considered at a conference are those stated in the conference notice (that is, the purpose of the conference, as discussed in current § 405.1040(b)).

Current § 405.1040(c) states that a record of the conference is made. However, that requirement has been read and applied differently by adjudicators. We are proposing at § 405.1040(c)(2) to require that an audio recording of the conference be made to establish a consistent standard and because the audio recording is the most administratively efficient way to make a record of the conference. We are proposing at § 423.2040(e)(1) and (e)(2) to adopt corresponding revisions to reference a conference notice and clarify that an audio recording of the conference is made in part 423, subpart U proceedings.

Current § 405.1040(d) requires the ALJ to issue an order stating all agreements and actions resulting from the conference. If the parties do not object, the agreements and actions become part of the hearing record and are binding on all parties. It does not state to whom a conference order is issued, and again broadly references parties in indicating who may object to the order. In addition, current § 405.1040(d) does not establish a time period within which an objection must be made before the order becomes part of the record and binding on the parties. Therefore, we are proposing to revise § 405.1040(d) to state that the ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. If a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties. Proposed § 405.1040(d) would provide that the order is issued to the parties and participants who attended the conference to help ensure the appropriate parties and participants receive the order, but as in current § 405.1040(d), only a party could object to the order. Proposed § 405.1040(d) would also establish that an objection must be made within 10 calendar days of receiving the order to establish a consistent minimum standard for making objection to a conference order, but would also provide the ALJ with the discretion to grant additional time. In addition, proposed § 405.1040(d) would replace "hearing record" with "administrative record" for consistency with other references to the record. Further, proposed § 405.1040(d) would continue to only allow the ALJ to issue a conference order, because we believe the ALJ should review and approve the actions and agreements resulting from the conference, and only an ALJ should issue an order that would be binding on the parties, if no objection is made. We are proposing at § 423.2040(f) to adopt corresponding revisions to clarify to whom a conference order is sent and the time frame to object to the order, and to specify that agreements and actions resulting from the conference become part of the "administrative record" (rather than "hearing record") in part 423, subpart U proceedings. However, we are proposing to add that an enrollee must object to a conference order within 1 calendar day of receiving the order for expedited hearings because of the abbreviated time frame under which an expedited hearing and decision must be completed.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Prehearing and posthearing conferences" at the beginning of your comment.

t. The Administrative Record (§§ 405.1042 and 423.2042)

The administrative record is HHS's record of the administrative proceedings, and is initially established by OMHA ALJs and built from the records of CMS contractors that adjudicated the claim, or from records maintained by SSA in certain circumstances. After adjudication by OMHA, the Council may include more documents in the administrative record, if a request for Council review is filed or a referral to the Council is made. If a party then seeks judicial review, the administrative record is certified and presented to the Court as the official agency record of the administrative proceedings. The record is returned to the custody of CMS contractors or SSA after any administrative and judicial review is complete. Current practices in creating the administrative record in accordance with current §§ 405.1042 and 423.2042 vary widely. Given the importance of the administrative record, we are proposing to revise §§ 405.1042 and 423.2042 to provide for more consistency and to clarify its contents and other administrative matters.

Current § 405.1042(a)(1) provides that the ALJ makes a complete record of the evidence, including the hearing proceedings, if any. However, this provision has been limiting and causes confusion in developing procedures to ensure the completeness of the record and in bringing consistency to how the record is structured because individual adjudicators organize the record differently. We are proposing to revise § 405.1042(a)(1) to require OMHA to make a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted. Proposed § 405.1042(a)(1) would vest OMHA, rather than the ALJ, with the responsibility of making a complete record of the evidence and administrative proceedings in the appealed matter, including any prehearing and posthearing conferences and hearing proceedings. This would provide OMHA with more discretion to develop polices and uniform procedures for constructing the administrative record, while preserving the role of the ALJ or attorney adjudicator, as proposed in section II.B above, to identify the evidence that was used in making the determinations below and the evidence that was used in making his or her decision. We are proposing at § 423.2042(a)(1) to also adopt corresponding revisions to indicate OMHA makes a complete record of the evidence and administrative proceedings in the appealed matter in part 423, subpart U proceedings.

Current § 405.1042(a)(2) discusses which documents in the record are marked as exhibits, and provides a non-exhaustive list of documents that are marked to indicate that they were considered in making the decisions under review or the ALJ's decision. It further states that in the record, the ALJ also must discuss any evidence excluded under § 405.1028 and include a justification for excluding the evidence. We are proposing to revise § 405.1042(a)(2) to state that the record would include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney admits. We are proposing that attorney adjudicators could mark exhibits because as proposed in section II.B, attorney adjudicators would be adjudicating requests for hearing and requests for review of a QIC dismissal, and should indicate the portions of the record that he or she considered in making the decision in the same manner as an ALJ. Proposed § 405.1042(a)(2) would continue to require certain evidence to be marked as exhibits, but would clarify what would be marked, replacing "the documents used in making the decision under review," with "the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision." We believe this would clarify that the exhibited portion of the record includes, at minimum, the appealed determinations, documents and other evidence used in making the appealed determinations, and documents and other evidence used in making the ALJ's or attorney adjudicator's decision. The illustrative list of documents that may be marked as exhibits pursuant to the rule in current § 405.1042(a)(2) would be incorporated in proposed § 405.1042(a)(2) without change. We also are proposing to clarify at § 405.1042(a)(2) that the record would include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party. All evidence presented should be included in the record, even if excluded from consideration, in order to help ensure a complete record of the evidence. However, such excluded evidence would not be marked as an exhibit because the evidence was not considered in making the ALJ's or attorney adjudicator's decision. We are proposing at § 423.2042(a)(2) to adopt corresponding revisions to clarify what would be exhibited in part 423, subpart U proceedings, except the reference to new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established as an example of evidence excluded or not considered by the ALJ or attorney adjudicator, because there is no such limitation on new evidence in part 423, subpart U proceedings.

As stated previously, current § 405.1042(a)(2) includes requirements to discuss any evidence excluded under current § 405.1028 and include a justification for excluding the evidence. We are proposing in § 405.1042(a)(2) to remove these requirements. We believe the requirement to justify excluding the evidence is not necessary and is in tension with the requirement for a provider or supplier, or beneficiary represented by a provider or supplier, to establish good cause for submitting new evidence before it may be considered. Section 1869(b)(3) of the Act establishes a general prohibition on new evidence that must be overcome, and proposed § 405.1028 would implement the statute by requiring the party to explain why the evidence was not submitted prior to the QIC reconsideration, and the ALJ or attorney adjudicator to make a finding of good cause to admit the evidence. In place of the current § 405.1042(a)(2) requirement, as we discuss later, we are proposing at § 405.1046(a)(2)(ii) to require that if new evidence is submitted for the first time at the OMHA level and subject to a good cause determination pursuant to proposed § 405.1028, the new evidence and good cause determination would be discussed in the decision. We believe the decision is the appropriate place to discuss the new evidence and document the good cause determination, and the discussion should focus on the good cause determination required by proposed § 405.1028, regardless of whether good cause was found. We are not proposing any corresponding changes to § 423.2042 because there is no provision equivalent to the current § 405.1042(a)(2) requirement to discuss any excluded evidence.

Current § 405.1042(a)(3) provides that a party may review the record "at the hearing," or if a hearing is not held, at any time before the ALJ's notice of decision is issued. However, this is rarely done in practice. More often, a party requests a copy of the record prior to the hearing, in accordance with current § 405.1042(b). We are proposing to revise § 405.1042(a)(3) to state that a party may request and review the record prior to or at the hearing, or if a hearing is not held, at any time before the notice of decision is issued. This revision would allow a party to request and review a copy of the record "prior to or at the hearing" to more accurately reflect the practices of parties. In addition, proposed § 405.1042(a)(3) would remove the reference to an "ALJ's" decision in explaining that if a hearing is not held, a party may request and review the record at any time before the notice of decision is issued, because in that circumstance an ALJ or attorney adjudicator, as proposed in section II.B, may issue the decision. We are proposing at § 423.2042(a)(3) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1042(a)(4) provides for the complete record, including any recording of the hearing, to be forwarded to the Council when a request for review is filed or the case is escalated to the Council. However, in noting that the record includes recordings, only a recording of the hearing is mentioned. We are proposing at § 405.1042(a)(4) to add that the record includes recordings of prehearing and posthearing conferences in addition to the hearing recordings, to reinforce that recordings of conferences are part of the complete record. We are proposing at § 423.2042(a)(4) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1042(b)(1) describes how a party may request and receive copies of the record from the ALJ. However, after a case is adjudicated, OMHA releases custody of the record and forwards it to a CMS contractor or SSA, and the record may go on to the Council for another administrative proceeding. This results in confusion for parties when they request a copy of the record and OMHA is unable to provide it. We are proposing at § 405.1042(b)(1) that a party may request and receive a copy of the record from OMHA while an appeal is pending at OMHA. We also are proposing at § 405.1042(b)(1) to replace the reference to an "exhibit list" with a reference to "any index of the administrative record" to provide greater flexibility in developing a consistent structure for the administrative record. We also are proposing to change the parallel reference to "the exhibits list" in § 405.1118 to "any index of the administrative record." In addition, proposed § 405.1042(b)(1) would replace the reference to a "tape" of the oral proceeding with an "audio recording" of the oral proceeding because tapes are no longer used and a more general reference would accommodate future changes in recording formats. We also are proposing to replace a parallel reference at § 405.1118 to a copy of the "tape" of the oral proceedings with a copy of the "audio recording" of the oral proceedings. We are proposing at §§ 423.2042(b)(1) and 423.2118 to adopt corresponding revisions for part 423, subpart U proceedings, but note that current § 423.2118 refers to a "CD" of the oral proceedings.

Current § 405.1042(b)(2) provides that if a party requests all or part of the record from an ALJ and an opportunity to comment on the record, the time beginning with the ALJ's receipt of the request through the expiration of the time granted for the party's response does not count toward the 90 calendar day adjudication period. We are proposing to revise § 405.1042(b)(2) to state, if a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response. This proposed revision would clarify that a party may request a "copy of" all or part of the record, and would add that the request may be made to OMHA, or the ALJ or attorney adjudicator, because a party may request a copy of the record before it is assigned to an ALJ or attorney adjudicator. In addition, proposed § 405.1042(b)(2) would revise the discussion of the effect of requesting an opportunity to comment on the record on an adjudication period to remove the specific reference to a 90 calendar day adjudication period, because in accordance with proposed § 405.1016, an adjudication period may be 90 or 180 calendar days, or alternatively may be waived by the appellant and therefore not apply. We are proposing at § 423.2042(b)(2) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1042 does not address the circumstance in which a party requests a copy of the record but is not entitled to receive some of the documents in the record. For example, when an appeal involves multiple beneficiaries and one beneficiary requests a copy of the record, the records related to other beneficiaries may not be released to the requesting beneficiary unless he or she obtains consent from the other beneficiaries to release the records that pertain to them. Proposed § 405.1042(b)(3) would address the possibility that a party requesting a copy of the record is not entitled to receive the entire record. Specifically, we are proposing in § 405.1042(b)(3) that if a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not entitled to receive (for example, personally identifiable information or protected health information), those portions of the record would not be furnished unless the requesting party obtains consent from the individual. For example, if a beneficiary requests a copy of the record for an appeal involving multiple beneficiaries, the portions of the record pertaining to the other beneficiaries would not be furnished to the requesting beneficiary unless he or she obtains consent from the other beneficiaries. We believe proposed § 405.1042(b)(3) would help ensure that parties are aware that they may not be entitled to receive all portions of the record. We are proposing at § 423.2042(b)(3) to adopt corresponding revisions for part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "The administrative record" at the beginning of your comment.

u. Consolidated Proceedings (§§ 405.1044 and 423.2044)

Current §§ 405.1044 and 423.2044 explain that a consolidated hearing may be held at the request of an appellant or on the ALJ's own motion, if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ, and CMS is notified of an ALJ's intention to conduct a consolidated hearing. If a consolidated hearing is conducted, current §§ 405.1044 and 423.2044 further provide that the ALJ may make a consolidated decision and record for the claims involved in the consolidated hearing, or may make a separate decision and record for each claim involved in the consolidated hearing. This authority is useful in allowing an ALJ and the appellant to conduct a single proceeding on multiple appealed claims or other determinations that are before the ALJ, reducing time and expense for the appellant and the government to resolve the appealed matter. However, the current provisions have caused confusion, and have been limiting in circumstances in which no hearing is conducted.

Current § 405.1044 uses the terms "requests for hearing," "cases," and "claims" interchangeably, which has resulted in confusion because an appeal, or "case," before an ALJ may involve multiple requests for hearing, if an appellant's requests were combined into one appeal for administrative efficiency prior to being assigned to the ALJ. In addition, a request for hearing may involve one or more claims. We are proposing in § 405.1044 to use the term "appeal" to specify that appeals may be consolidated for hearing, and a single decision and record may be made for consolidated appeals. We are proposing to use "appeal" because an appeal is assigned a unique ALJ appeal number, for which a unique decision and record is made. We also are proposing to move current § 405.1044(b) to new subsection (a)(2), and to also replace the term "combined" with "consolidated" for consistent use in terminology. Further, we are proposing at § 423.2044 to adopt corresponding revisions to use consistent terminology in part 423, subpart U proceedings.

Current § 405.1044(a) through (d) describes when a consolidated hearing may be conducted, the effect on an adjudication period that applies to the appeal, and providing notice of the consolidated hearing to CMS. Proposed § 405.1044(a) would incorporate current § 405.1044(a) through (c) to combine the provisions related to a consolidated hearing. In addition, proposed § 405.1044(a)(4) would replace the current requirement to notify CMS that a consolidated hearing will be conducted in current § 405.1044(d) with a requirement to include notice of the consolidated hearing in the notice of hearing issued in accordance with §§ 405.1020 and 405.1022. This would help ensure notice is provided to the parties and CMS, as well as its contractors, in a consistent manner, and reduce administrative burden on ALJs and their staff by combining that notice into the existing notice of hearing. We are proposing at § 423.2044(a) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1044(e) explains that when a consolidated hearing is conducted, the ALJ may consolidate the record and issue a consolidated decision, or the ALJ may maintain separate records and issue separate decisions on each claim. It also states that the ALJ ensures that any evidence that is common to all claims and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable. However, there has been confusion on whether separate records may be maintained and a consolidated decision can be issued, as well as what must be included with the records when separate records are maintained. Proposed § 405.1044(b) would incorporate some of current § 405.1044(e) and add provisions for making a consolidated record and decision. We are proposing at § 405.1044(b)(1) that if the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record, or a separate decision and record on each appeal. This proposed revision would maintain the current option to make a consolidated record and decision, or maintain separate records and issue separate decisions, but restructures the provision to highlight that these are two mutually exclusive options. This proposal is important because issuing a consolidated decision without also consolidating the record, or issuing separate decisions when a record has been consolidated, complicates effectuating a decision and further reviews of the appeal(s). We are proposing in § 405.1044(b)(2) that, if a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record. Proposed § 405.1044(b)(2) would address the confusion that sometimes results in a copy of the audio recording of a consolidated hearing not being included in the administrative records of each constituent appeal when separate records are maintained, by clarifying that if a separate decision and record is made, audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual record. This proposal is important because the record for each individual appeal must be complete. We are proposing at § 423.2044(b)(1) and (b)(2) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1044 does not contemplate a consolidated record and decision unless a consolidated hearing was conducted, which is limiting when multiple appeals for an appellant can be consolidated in a decision issued on the record without a hearing. We are proposing to add § 405.1044(b)(3), which would provide that, if a hearing would not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator as proposed in section II.B, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the appellant or on the ALJ's or attorney adjudicator's own motion. This would provide authority for an ALJ or attorney adjudicator to make a consolidated decision and record on the same basis that a consolidated hearing may be conducted. We believe this authority would add efficiency to the adjudication process when multiple appeals pending before the same adjudicator can be decided without conducting a hearing. We are proposing at § 423.2044(b)(3) to adopt a corresponding provision for part 423, subpart U proceedings.

Current § 405.1044 also does not clearly address consolidating hearings for multiple appellants, including situations in which a beneficiary files a request for hearing on the same claim appealed by a provider or supplier, and the provider or supplier has other pending appeals that could be consolidated pursuant to current § 405.1044. The general practice is that a consolidated hearing is conducted for the appeals of a single appellant. This is supported by the reference to "an" appellant in current § 405.1044(b), and helps ensure the hearing and record is limited to protected information that the appellant is authorized to receive. Therefore, we are proposing to add § 405.1044(c) to provide that consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement in accordance with § 405.1006, and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants. This would help ensure that beneficiary information is protected from disclosure to parties who are not authorized to receive it, including when a beneficiary requests a hearing for the same claim that has been appealed by a provider or supplier, and appeals of other beneficiaries' claims filed by the provider or supplier are also pending before the same ALJ or attorney adjudicator. We are proposing at § 423.2044(c) to adopt a corresponding provision for part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Consolidated proceedings" at the beginning of your comment.

v. Notice of Decision and Effect of an ALJ's or Attorney Adjudicator's Decision (§§ 405.1046, 405.1048, 423.2046, and 423.2048)

Current §§ 405.1046 and 423.2046 describe the requirements for a decision and providing notice of the decision, the content of the notice, the limitation on a decision that addresses the amount of payment for an item or a service, the timing of the decision, and recommended decisions. Current §§ 405.1048 and 423.2048 describe the effects of an ALJ's decision. However, the current sections only apply to a decision on a request for hearing, leaving ambiguities when issuing a decision on a request for review of a QIC or IRE dismissal. We are proposing to consolidate the provisions of each section that apply to a decision on a request for hearing under proposed §§ 405.1046(a), 405.1048(a), 423.2046(a) and 423.2048(a), with further revisions discussed below, and introduce new §§ 405.1046(b), 405.1048(b), 423.2046(b) and 423.2048(b) to address a decision on a request for review of a QIC or IRE dismissal, as well as to revise the titles and provisions of the sections to expand their coverage to include decisions by attorney adjudicators, as proposed in II.B above. We also are proposing to remove current § 405.1046(d), which addresses the timing of a decision on a request for hearing because it is redundant with § 405.1016 and could lead to confusion if a different adjudication period applies, such as a 180-calendar day period for an escalated request for QIC reconsideration, or if no adjudication period applies, such as when the period is waived by the appellant. Similarly, we are proposing to remove current §§ 423.2046(a)(1) and (d) because the adjudication time frames discussed in the provisions are redundant with provisions in proposed § 423.2016. In addition, we are proposing to re-designate current §§ 405.1046(e) and 423.2046(e), as proposed §§ 405.1046(c) and 423.2046(c) respectively, to reflect the revised structure of proposed §§ 405.1046 and 423.2046.

Current § 405.1046 states that an ALJ will issue a decision unless a request for hearing is dismissed. We are proposing to revise § 405.1046(a) to state that an ALJ or attorney adjudicator would issue a decision unless the request for hearing is dismissed or remanded in order to accommodate those situations where the ALJ or attorney adjudicator remands a case to the QIC. There has been confusion regarding the content requirements of the decision itself, as well as whether the findings or conclusions in a QIC reconsideration or the arguments of the parties may be referenced or adopted in the decision by reference. We believe that while the issues that are addressed in a decision are guided by the reconsideration, as well as the initial determination and redetermination, and a party may present arguments in a framework that reflects recommended findings and conclusions, the concept of a de novo review requires an ALJ or attorney adjudicator to make independent findings and conclusions. To address this confusion, we are proposing in § 405.1046(a) to require that the decision include independent findings and conclusions to clarify that the ALJ or attorney adjudicator must make independent findings and conclusions, and may not merely incorporate the findings and conclusions offered by others, though the ALJ or attorney adjudicator may ultimately make the same findings and conclusions. As discussed in and for the reasons stated in section III.A.3.t above, proposed § 405.1046(a)(2)(ii) would also require that if new evidence was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to proposed § 405.1028, the new evidence and good cause determination would be discussed in the decision. We are proposing at § 423.2046(a) to adopt corresponding revisions for decisions on requests for hearing under part 423, subpart U, except the proposals related to discussing new evidence and good cause determinations related to new evidence because there are no current requirements to establish good cause for submitting new evidence in part 423, subpart U proceedings.

Current § 405.1046(a) requires that a decision be mailed. As OMHA transitions to a fully electronic case processing and adjudication environment, new options for transmitting a decision to the parties and CMS contractors may become available, such as through secure portals for parties or through inter-system transfers for CMS contractors. We are proposing in § 405.1046(a) to revise the requirement that a decision be mailed to state that OMHA "mails or otherwise transmits a copy of the decision," to allow for additional options to transmit the decision as technologies develop. We are proposing to revise § 423.2046(a) to adopt a corresponding revision for sending a decision under part 423, subpart U.

Current § 405.1046(a) also requires that a copy of the decision be sent to the QIC that issued the reconsideration. However, if the decision is issued pursuant to escalation of a request for a reconsideration, no reconsideration was issued. To address this circumstance, we are proposing in § 405.1046(a) that the decision would be issued to the QIC that issued the reconsideration or from which the appeal was escalated. In addition, we are proposing in § 405.1046(a) to replace "reconsideration determination" with "reconsideration" for consistency in referencing the QIC's action. Current § 405.1046(a) also requires that a copy of the decision be sent to the contractor that made the initial determination. However, this requirement adds to the administrative burden on OMHA and we believe is unnecessary in light of the requirement that a copy of the decision be sent to the QIC and the original decision is forwarded as part of the administrative record to another CMS contractor to effectuate the decision. Thus, we are proposing in § 405.1046(a) to remove the requirement to send a copy of the decision to the contractor that issued the initial determination. In addition, we are proposing in § 423.2046(a) to replace "reconsideration determination" with "reconsideration" for consistency in referencing the IRE's action in part 423, subpart U proceedings, but we are not proposing to incorporate other changes proposed for § 405.1046(a) in proposed § 423.2046(a) because: (1) escalation is not available in part 423, subpart U proceedings; and (2) the Part D plan sponsor, which makes the initial coverage determination, has an interest in receiving and reviewing ALJ and attorney adjudicator decisions related to an enrollee's appeal of drug coverage.

As discussed above, we are proposing to revise § 405.1046(b) to explain the process for making a decision on a request for review of a QIC dismissal. In accordance with proposed § 405.1004, we are proposing in § 405.1046(b)(1) that unless the ALJ or attorney adjudicator dismisses the request for review of a QIC's dismissal or the QIC's dismissal is vacated and remanded, the ALJ or attorney adjudicator issues a written decision affirming the QIC's dismissal. We are proposing in § 405.1046(b)(1) that OMHA would mail or otherwise transmit a copy of the decision to all the parties that received a copy of the QIC's dismissal because we believe that the QIC would appropriately identify the parties who have an interest in the dismissal, and that notice of the decision on a request for review of a QIC dismissal to any additional parties is unnecessary. We also believe that notice to the QIC is not necessary when its dismissal is affirmed because it has no further obligation to take action on the request for reconsideration that it dismissed. We are proposing in § 405.1046(b)(2)(i) that the decision affirming a QIC dismissal must describe the specific reasons for the determination, including a summary of the evidence considered and applicable authorities, but are not proposing to require a summary of clinical or scientific evidence because such evidence is not used in making a decision on a request for a review of a QIC dismissal. In addition, we are proposing that § 405.1046(b)(2)(ii) and (iii) would explain that the notice of decision would describe the procedures for obtaining additional information concerning the decision, and would provide notification that the decision is binding and not subject to further review unless the decision is reopened and revised by the ALJ or attorney adjudicator. We are proposing to revise § 423.2046(b) to adopt corresponding provisions for a decision on requests for review of an IRE dismissal under part 423, subpart U, except that the notice of decision will only be sent to the enrollee because only the enrollee is a party.

We are proposing to revise the title of current § 405.1048 to read "The effect of an ALJ's or attorney adjudicator's decision" and to replace the current introductory statement in § 405.1048(a) that "The decision of the ALJ is binding on all parties to the hearing" with "The decision of the ALJ or attorney adjudicator is binding on all parties" to make the subsection applicable to decisions by attorney adjudicators and because the parties are parties to the decision regardless of whether a hearing was conducted. We also are proposing in § 405.1048(b) that the decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures explained in § 405.980. We are proposing to revise § 423.2048 to adopt corresponding provisions for the effects of ALJ and attorney adjudicator decisions under part 423, subpart U.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Notice of decision and effect of an ALJ's or attorney adjudicator's decision" at the beginning of your comment.

w. Removal of a Hearing Request From an ALJ to the Council (§§ 405.1050 and 423.2050)

Current §§ 405.1050 and 423.2050 explain the process for the Council to assume responsibility for holding a hearing if a request for hearing is pending before an ALJ. We are proposing to replace "an ALJ" with "OMHA" in the section title, and to replace "pending before an ALJ" with "pending before OMHA," and "the ALJ send" with "OMHA send" in the section text. In accordance with section II.B above, these proposed revisions would provide that a request for hearing may be removed to the Council regardless of whether the request is pending before an ALJ or an attorney adjudicator. We are not proposing to replace the last instance of "ALJ" in the section text because it refers specifically to hearings conducted by an ALJ.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Removal of a hearing request from an ALJ to the Council" at the beginning of your comment.

x. Dismissal of a Request for Hearing or Request for Review and Effect of a Dismissal of a Request for Hearing or Request for Review (§§ 405.1052, 405.1054, 423.2052 and 423.2054)

Current §§ 405.1052 and 423.2052 describe the circumstances in which a request for hearing may be dismissed and the requirements for a notice of dismissal, and current §§ 405.1054 and 423.2054 describe the effect of a dismissal of a request for hearing. However, both current sections apply to a dismissal of a request for hearing, leaving ambiguities when issuing a dismissal of a request for review of a QIC or IRE dismissal. We are proposing to maintain the provisions of each section that apply to a dismissal of a request for hearing in proposed §§ 405.1052(a), 405.1054(a), 423.2052(a) and 423.2054(a), with further revisions discussed below, and to introduce new §§ 405.1052(b), 405.1054(b), 423.2052(b) and 423.2054(b) to address a dismissal of a request for review of a QIC or IRE dismissal. However, we are proposing to re-designate and revise §§ 405.1052(a)(1) and 423.2052(a)(1), as discussed below, and re-designate the remaining paragraphs in §§ 405.1052(a) and 423.2052(a) accordingly. We are also proposing to remove the introductory language to current §§ 405.1052 and 423.2052 because it is unnecessary to state that a dismissal of a request for hearing is in accordance with the provisions of the section, as the provisions are themselves binding authority and state in full when a request for hearing may be dismissed. In addition, we are proposing to revise the titles of the sections to expand their coverage to include dismissals of requests to review a QIC or IRE dismissal. Furthermore, we are proposing to re-designate and revise current §§ 405.1052(b) and 423.2052(b), which describe notices of dismissal, as proposed §§ 405.1052(d) and 423.2052(d) respectively, to reflect the revised structure of proposed §§ 405.1052 and 423.2052. We also are proposing to remove current § 423.2052(a)(8) and (c) because current § 423.2052(a)(8) restates current § 423.1972(c)(1), which already provides that a request for hearing will be dismissed if the request itself shows that the amount in controversy is not met, and current § 423.2052(c) restates current § 423.1972(c)(2), which already provides that if after a hearing is initiated, the ALJ finds that the amount in controversy is not met, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal. We note that a dismissal would be warranted in these circumstances pursuant to current § 423.2052(a)(3), which is carried over as proposed § 423.2052(a)(2) because the enrollee does not have a right to a hearing if the amount in controversy is not met.

We are proposing to re-designate and revise current §§ 405.1052(a)(1) and 423.2052(a)(1) as proposed §§ 405.1052(c) and 423.2052(c) to separately address dismissals based on a party's withdrawal. We are proposing in §§ 405.1052(c) and 423.2052(c) to include withdrawals of requests to review a QIC dismissal because we also propose to add provisions to address other dismissals of those requests at §§ 405.1052(b) and 423.2052(b). We also are proposing that an ALJ or attorney adjudicator may dismiss a request for review of a QIC dismissal based on a party's withdrawal of his or her request because as proposed in section II.B above, both ALJs and attorney adjudicators would be able to adjudicate requests to review a QIC dismissal. In addition, we are proposing that an ALJ or attorney adjudicator may dismiss a request for hearing based on a party's withdrawal of his or her request. As discussed in section II.B above, we believe that well-trained attorneys can efficiently perform a review of these requests and issue dismissals. We believe using attorney adjudicators to the maximum extent possible would help OMHA be more responsive to appellants and allow ALJs to focus on conducting hearings and issuing decisions. We also are proposing to revise the language in current §§ 405.1052(a)(1) and 423.2052(a)(1) (as redesignated in proposed §§ 405.1052(c) and 423.2052(c)) to (1) replace "notice of the hearing decision" with "notice of the decision, dismissal or remand" to reflect that a decision may be issued without a hearing, and to reflect other possible outcomes of the proceeding (dismissal and remand), and (2) to clarify that a request to withdraw a request for hearing may be made orally at a hearing before the ALJ because only an ALJ may conduct a hearing.

Current § 405.1052(a)(2) describes three possible alternatives for dismissing a request for hearing when the party that requested the hearing, or the party's representative, does not appear at the time and place set for the hearing. The current alternatives have caused confusion for appellants in understanding whether they are required to submit a statement explaining a failure to appear. Further, current provisions do not require evidence in the record to document an appellant was aware of the time and place of the hearing, and this has resulted in remands from the Council. We are proposing to simplify the provision to provide two alternatives, and to require that contact has been made with an appellant and documented, or an opportunity to provide an explanation for failing to appear has been provided before a request for hearing is dismissed for failing to appear at the hearing. We are proposing at § 405.1052(a)(1)(i) to set forth the first alternative which would provide that a request for hearing may be dismissed if the party that filed the request was notified before the time set for hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar days after the hearing or does contact the ALJ but does not provide good cause for not appearing. We are proposing at § 405.1052(a)(1)(ii) to set forth the second alternative which would provide that a request for hearing may be dismissed if the record does not contain documentation that the party acknowledged the notice of hearing, but the ALJ sends a notice to the party at his or her last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does respond but does not provide good cause for not appearing. In either circumstance, we are maintaining in proposed § 405.1052(a)(1) the current standard that in determining whether good cause exists, the ALJ considers any physical, mental, educational, or linguistic limitations that the party may have identified. We believe proposed § 405.1052(a)(1) would help ensure that appellants have consistent notice of a possible dismissal for failure to appear and an opportunity to provide a statement explaining why they did not appear before a dismissal is issued. We are proposing to revise § 423.2052(a)(1) to adopt corresponding revisions for dismissing a request for hearing under part 423, subpart U.

Current OMHA policy provides that a request for hearing that does not meet the requirements of current § 405.1014 may be dismissed by an ALJ after an opportunity is provided to the appellant to cure an identified defect (OMHA Case Processing Manual, division 2, chapter 3, section II–3–6 D and E). A dismissal is appropriate because as an administrative matter, the proceedings on the request do not begin until the information necessary to adjudicate the request is provided and the appellant sends a copy of the request to the other parties. Additionally, a request cannot remain pending indefinitely once an appellant has demonstrated that he or she is unwilling to provide the necessary information or to send a copy of the request to the other parties. Therefore, we are proposing at § 405.1052(a)(7) to explain that a request for hearing may be dismissed if the request is not complete in accordance with proposed § 405.1014(a)(1) or the appellant did not send copies of its request to the other parties in accordance with proposed § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send copies of the request to the other parties. We believe adding this provision would emphasize the importance of following the requirements for filing a request for hearing, and clarify the outcome if the requirements are not met and the appellant does not cure identified defects after being provided with an opportunity to do so. We are proposing at § 423.2052(a)(7) to adopt a corresponding provision for dismissing a request for hearing under part 423, subpart U.

As discussed above, we are proposing to add § 405.1052(b) to explain when a request for review of a QIC dismissal would be dismissed. Under proposed § 405.1052(b), a request for review could be dismissed in the following circumstances: (1) the person or entity requesting the review has no right to the review of the QIC dismissal under proposed § 405.1004; (2) the party did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline; (3) a beneficiary or beneficiary's representative filed the request for review and the beneficiary passed away while the request for review is pending and all of the following criteria apply: (i) a surviving spouse or estate has no remaining financial interest in the case, (ii) no other individuals or entities have a financial interests in the case and wish to pursue an appeal, and (iii) no other individual or entity filed a valid and timely request for a review of the QIC dismissal; and (4) the appellant's request for review is not complete in accordance with proposed § 405.1014(a)(1) or the appellant does not send a copy of the request to the other parties in accordance with proposed § 405.1014(d), after being provided with an opportunity to complete the request and/or send a copy of the request to the other parties. We believe these provisions would encompass the reasons for dismissing a request for a review of a QIC dismissal, and are necessarily differentiated from dismissing a request for hearing because, as explained in section III.A.3.c above, we do not believe there is a right to a hearing for requests for a review of a QIC dismissal. We are proposing at § 423.2052(b) to adopt corresponding provisions for dismissing requests for a review of an IRE dismissal under part 423, subpart U proceedings.

As discussed above, current § 405.1052(b) describes the requirements for providing notice of the dismissal and we are proposing to re-designate the paragraph as proposed § 405.1052(d). For the same reasons discussed in section III.A.3.v above for allowing a notice of a decision to be provided by means other than mail, we are proposing in § 405.1052(d) that OMHA may mail or "otherwise transmit" notice of a dismissal. We are proposing to revise § 423.2052(d) to adopt a corresponding revision for notices of dismissal under part 423, subpart U.

Current § 405.1052(b) requires notice of the dismissal to be sent to all parties at their last known address. However, we believe that requirement is overly inclusive and causes confusion by requiring notice of a dismissal to be sent to parties who have not received a copy of the request for hearing or request for review that is being dismissed. Thus, we are proposing to revise § 405.1052(d) to state that the notice of dismissal is sent to the parties who received a copy of the request for hearing or request for review because only those parties are on notice that a request was pending. In addition, we are proposing at § 405.1052(d) that if a party's request for hearing or request for review is dismissed, the appeal would proceed with respect to any other parties who also filed a valid request for hearing or review regarding the same claim or disputed matter. This would address the rare circumstance in which more than one party submits a request, but the request of one party is dismissed. In that circumstance, the appeal proceeds on the request that was not dismissed, and the party whose request was dismissed remains a party to the proceedings but does not have any rights associated with a party that filed a request, such as the right to escalate a request for hearing. We are not proposing a corresponding revision to § 423.2052(c) because only the enrollee is a party to an appeal under part 423, subpart U.

Current § 405.1052 does not include authority for an ALJ to vacate his or her own dismissal, and instead requires an appellant to request the Council review an ALJ's dismissal. As explained in the 2005 Interim Final Rule (70 FR 11465), the authority for an ALJ to vacate his or her own dismissal was not regarded as an effective remedy because the record was no longer in the ALJ hearing office, and the resolution was complicated when appellants simultaneously asked the ALJ to vacate the dismissal order and asked the Council to review the dismissal. However, in practice, the lack of the authority for an ALJ to vacate his or her own dismissal has constrained ALJs' ability to correct erroneous dismissals that can be easily remedied by the ALJ, and has caused unnecessary work for the Council. We are proposing to add § 405.1052(e) to provide the authority for an ALJ or an attorney adjudicator, as proposed in section II.B above, to vacate his or her own dismissal within 6 months of the date of the notice of dismissal, in the same manner as a QIC can vacate its own dismissal. We believe that this authority would reduce unnecessary appeals to the Council and provide a more timely resolution of dismissals for appellants, whether the dismissal was issued by an ALJ or attorney adjudicator. We also note that the coordination for obtaining the administrative record and addressing instances in which an appellant also requests a review of the dismissal by the Council can be addressed through operational coordination among CMS, OMHA, and the DAB. We are proposing in § 423.2052(e) to adopt a corresponding provision for vacating a dismissal under part 423, subpart U.

To align the effects of a dismissal with proposed § 405.1052(e), we are proposing to add § 405.1054(a) to state that the dismissal of a request for hearing is binding unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e), in addition to the current provision that allows the dismissal to be vacated by the Council under § 405.1108(b). To explain the effect of a dismissal of a request for review of a QIC dismissal, consistent with § 405.1004, we are proposing in § 405.1054(b) to provide that the dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e). We are proposing in § 423.2054 to adopt corresponding revisions for the effect of dismissals of request for hearing and requests for review of an IRE dismissal under part 423, subpart U.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Dismissal of a request for hearing or request for review and effect of a dismissal of a request for hearing or request for review" at the beginning of your comment.

4. Applicability of Medicare Coverage Policies (§§ 405.1060, 405.1062, 405.1063, 423.2062, 423.2063)

Current § 405.1060 addresses the applicability of national coverage determinations (NCDs) to claim appeals brought under part 405, subpart I and provides that an ALJ and the Council may not disregard, set aside, or otherwise review an NCD, but may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim. Current § 405.1062 addresses the applicability of local coverage determinations (LCDs) and other policies, and specifies that ALJs and the Council are not bound by LCDs, local medical review policies (LMRPs), or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case, and if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or the Council must explain the reasons why the policy was not followed. Similarly, current § 423.2062 states that ALJs and the Council are not bound by CMS program guidance but will give substantial deference to these policies if they are applicable to a particular case, and if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or the Council must explain the reasons why the policy was not followed. Current §§ 405.1062 and 423.2062 also provide that an ALJ or Council decision to disregard a policy applies only to the specific claim being considered and does not have precedential effect. Further, § 405.1062 states that an ALJ or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. Current §§ 405.1063 and 423.2063 address the applicability of laws, regulations, and CMS Rulings, and provide that all laws and regulations pertaining to the Medicare program (and for § 405.1063 the Medicaid program as well), including but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs and the Council, and consistent with § 401.108, CMS Rulings are binding on all HHS components that adjudicate matters under the jurisdiction of CMS.

We are proposing to revise §§ 405.1060, 405.1062, 405.1063, 423.2062, and 405.2063 to replace "ALJ" or "ALJs" with "ALJ or attorney adjudicator" or "ALJs or attorney adjudicators" except in the second sentence of § 405.1062(c). As proposed in section II.B above, an attorney adjudicator would issue certain decisions and dismissals and therefore would apply the authorities addressed by these sections. Requiring the attorney adjudicators to apply the authorities in the same manner as an ALJ would provide consistency in the adjudication process, regardless of who is assigned to adjudicate a request for an ALJ hearing or request for review of a QIC or IRE dismissal. We are not proposing to revise the second sentence in current § 405.1062(c) because attorney adjudicators would not review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 (part 426 appeals are currently heard by ALJs in the Civil Remedies Division of the DAB).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Applicability of Medicare Coverage Policies" at the beginning of your comment.

5. Council Review and Judicial Review

a. Council Review: General (§§ 405.1100, 423.1974 and 423.2100)

Current § 405.1100 discusses the Council review process. Current § 405.1100(a) states that the appellant or any other party to the hearing may request that the Council review an ALJ's decision or dismissal. We are proposing to revise § 405.1100(a) to replace "the hearing" with "an ALJ's or attorney adjudicator's decision or dismissal," and "an ALJ's decision or dismissal," with "the ALJ's or attorney adjudicator's decision or dismissal" because the parties are parties to the proceedings and the resulting decision or dismissal regardless of whether a hearing is conducted, and as proposed in section II.B above, an attorney adjudicator would be able to issue certain decisions or dismissals for which Council review maybe requested.

Current § 423.1974 states that an enrollee who is dissatisfied with an ALJ hearing decision may request that the Council review the ALJ's decision or dismissal as provided in § 423.2102, and current § 423.2100(a) states that consistent with § 423.1974, the enrollee may request that the Council review an ALJ's decision or dismissal. We are proposing to revise § 423.1974 to replace "ALJ hearing decision" with "an ALJ's or attorney adjudicator's decision or dismissal," and to revise §§ 423.1974 and 423.2100(a) to replace "ALJ's decision or dismissal" with "an ALJ's or attorney adjudicator's decision or dismissal" because the parties are parties to the proceedings and resulting decision or dismissal regardless of whether a hearing is conducted, and as proposed in section II.B above, an attorney adjudicator may issue a decision or dismissal for which Council review maybe requested.

Current § 405.1100(b) provides that under the circumstances set forth in §§ 405.1104 and 405.1108, an appellant may request escalation of a case to the Council for a decision even if the ALJ has not issued a decision or dismissal in his or her case. We are proposing to revise § 405.1100(b) to provide that under circumstances set forth in §§ 405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case. These revisions would reference § 405.1016, which, as discussed in section III.A.3.h above, would replace the current § 405.1104 provisions for escalating a case from the OMHA level to the Council. They would also provide that in addition to potentially issuing a decision or dismissal, an ALJ or attorney adjudicator, as proposed in section II.B above, may issue a remand—this would present a complete list of the actions that an ALJ or attorney adjudicator could take on an appeal.

Current §§ 405.1100(c) and 423.2100(b) and (c) state in part that when the Council reviews an ALJ's decision, it undertakes a de novo review, and the Council issues a final decision or dismissal order or remands a case to the ALJ. We are proposing to revise §§ 405.1100(c) and 423.2100(b) and (c) to state that when the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a de novo review and may remand a case to an ALJ or attorney adjudicator, so that the same standard for review is applied to ALJ and attorney adjudicator decisions. We are also proposing to revise §§ 405.1100(c) and 423.2100(c) to state that the Council may remand an attorney adjudicator's decision to the attorney adjudicator so that like an ALJ, the attorney adjudicator can take the appropriate action ordered by the Council (however, if the Council were to order that a hearing must be conducted, the case would be transferred to an ALJ upon remand to the attorney adjudicator because only an ALJ may conduct a hearing).

Current § 423.2100(c) and (d) provide that the Council issues a final decision, dismissal order, or remand no later than the period of time specified in the respective paragraph, beginning on the date that the request for review is received by the entity specified in the ALJ's written notice of decision. We are proposing to revise § 423.2100(c) and (d) to state that the period of time begins on the date that the request for review is received by the entity specified in the ALJ's or attorney adjudicator's written notice of decision because an attorney adjudicator may also issue a decision, as proposed in section II.B above. We are also proposing to revise § 423.2100(c) to correct a typographical error by inserting "day" into the current "90 calendar period," so it is clear to enrollees that the period of time being referenced is the 90 calendar day period.

Current § 405.1100(d) states in part that when deciding an appeal that was escalated from the ALJ level to the Council, the Council will issue a final decision or dismissal order or remand order within 180 calendar days of receipt of the appellant's request for escalation. A remand from the Council after an appeal is escalated to it is exceedingly rare and done in circumstances in which the Council must remand to an ALJ so that the ALJ may obtain information under current § 405.1034 that is missing from the written record and essential to resolving the issues on appeal, and that information can only be provided by CMS or its contractors, because the Council does not have independent authority to obtain the information from CMS or its contractors. In addition, an appeal may have not yet have been assigned to an ALJ, or could be assigned to an attorney adjudicator as proposed in section II.B above, when the appeal was escalated by the appellant. We are proposing to revise § 405.1100(d) to state that if the Council remands an escalated appeal, the remand is to the OMHA Chief ALJ because the rare and unique circumstances in which an escalated appeal is remanded by the Council require immediate attention that the OMHA Chief ALJ is positioned to provide to minimize delay for the appellant, and to minimize confusion if the case was not assigned to an ALJ or attorney adjudicator when it was escalated.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Medicare Appeals Council review: general" at the beginning of your comment.

b. Request for Council Review When the ALJ Issues Decision or Dismissal (§§ 405.1102 and 423.2102)

Current §§ 405.1102 and 423.2102 discuss requests for Council review when an ALJ issues a decision or dismissal. Current §§ 405.1102(a)(1) and 423.2102(a)(1) provide that a party or enrollee, respectively, to "the ALJ hearing" may request a Council review if the party or enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's decision or dismissal, which is in accordance with the criteria specified in current §§ 405.1102 and 423.2102. However, a party or enrollee is a party to the proceedings and resulting decision or dismissal, and may appeal the decision or dismissal regardless of whether a hearing was conducted in the appeal, and as proposed in section II.B above, an attorney adjudicator may issue a decision or dismissal for which Council review may be requested. To help ensure there is no confusion that a party or enrollee may seek Council review even if a hearing before an ALJ is not conducted or if an attorney adjudicator issues the decision or dismissal, we are proposing to revise §§ 405.1102(a)(1) and 423.2102(a)(1) to state a party or enrollee to a decision or dismissal issued by an ALJ or attorney adjudicator may request Council review if the party or enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

Current §§ 405.1102(c) and 423.2102(c) provide that a party or enrollee, respectively, does not have a right to seek Council review of an ALJ's remand to a QIC or IRE, or an ALJ's affirmation of a QIC's or IRE's dismissal of a request for reconsideration. However, under current §§ 405.1004(c) and 423.2004(c), a party or enrollee, respectively, may currently seek Council review of a dismissal of a request for review of a QIC or IRE dismissal because, as discussed in section III.A.3.x above, an ALJ does not currently have the authority to vacate his or her own dismissal. As proposed in section II.B above, an attorney adjudicator could adjudicate requests for a review of a QIC or IRE dismissal. In addition, proposed §§ 405.1052(e) and 423.2052(e) would establish the authority for an ALJ or attorney adjudicator to vacate his or her own dismissal, and in accordance with the policy that a review of a dismissal is only reviewable at the next level of appeal, as discussed in section III.A.3.c above, proposed §§ 405.1102(c) and 423.2102(c) would be revised to indicate that a party does not have the right to seek Council review of an ALJ's or attorney adjudicator's dismissal of a request for review of a QIC dismissal. Therefore, we are proposing at §§ 405.1102(c) and 423.2102(c) to add that a party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC or IRE, affirmation of a QIC's or IRE's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC or IRE dismissal.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Request for Council review when ALJ issues decision or dismissal" at the beginning of your comment.

c. Where a Request for Review or Escalation May Be Filed (§§ 405.1106 and 423.2106)

Current §§ 405.1106(a) and 423.2106 provide that when a request for a Council review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's action, and under § 405.1106, the appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal who received a copy of the hearing decision or notice of dismissal. The sections also explain that if the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action, and upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication time frame. In addition, current § 405.1106(b) discusses that if an appellant files a request to escalate an appeal to the Council because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under § 405.1016, the request for escalation must be filed with both the ALJ and the Council, and the appellant must also send a copy of the request for escalation to the other parties and failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for Council review.

We are proposing in §§ 405.1106 and 423.2106 to replace all instances of "ALJ" with "ALJ or attorney adjudicator," "ALJ's action" with "ALJ's or attorney adjudicator's action," to provide that the sections apply to decisions and dismissals issued by an attorney adjudicator as well, as proposed in section II.B, and therefore appellants would have the same right to seek Council review of the attorney adjudicator's decision or dismissal, and the Council would have the authority to take the same actions in reviewing an attorney adjudicator's decision or dismissal. We are also proposing to replace "a copy of the hearing decision under § 405.1046(a) or a copy of the notice of dismissal under § 405.1052(b)" in § 405.1106(a) with "notice of the decision or dismissal," because §§ 405.1046 and 405.1052 provide for notice of a decision or dismissal, respectively, to be sent, and a decision or dismissal may be issued by an ALJ or attorney adjudicator without conducting a hearing. In addition, in describing the consequences of failing to send a copy of the request for review to the other parties, we are proposing to replace "until all parties to the hearing" in

§ 405.1106(a) to "until all parties to the ALJ or attorney adjudicator decision or dismissal," to align the language with the preceding sentences.

We are proposing to revise § 405.1106(b) to align the paragraph with the revised escalation process proposed at § 405.1016 (see section III.A.3.h.i above). Specifically, we are proposing to revise § 405.1106(b) to state that if an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under § 405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. This proposed revision would align this section with the revised process in proposed § 405.1016 by specifying that the request for escalation is filed with OMHA and removing the requirement for an appellant to also file the request with the Council. In addition, proposed § 405.1106(b) would specify that the request for escalation must be sent to the other parties who were sent a copy of the QIC reconsideration, which would align with the parties to whom the appellant is required to send a copy of its request for hearing. Proposed § 405.1106(b) would also refer to "an applicable adjudication period" under § 405.1016, to align the terminology and because an adjudication period may not apply to a specific case (for example, if the appellant waived an applicable adjudication time frame). Finally, proposed § 405.1106(b) would provide that failing to copy the other parties would toll the Council's adjudication deadline until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation, rather than notice of the request for Council review as is currently required, because the revised escalation process proposed at § 405.1016 would remove the requirement to file a request for Council review when escalation is requested from the OMHA to the Council level.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Where a request for review or escalation may be filed" at the beginning of your comment.

d. Council Actions When Request for Review or Escalation Is Filed (§§ 405.1108 and 423.2108)

Current §§ 405.1108 and 423.2108 describe the actions the Council may take upon receipt of a request for review or, for § 405.1108, a request for escalation. We are proposing at § 405.1108(d) introductory text to replace "ALJ level" with "OMHA level" to provide that the Council's actions with respect to a request for escalation are the same regardless of whether the case was pending before an ALJ or attorney adjudicator, or unassigned at the time of escalation. We are also proposing at § 405.1108(d)(3) to replace "remand to an ALJ for further proceedings, including a hearing" with "remand to OMHA for further proceedings, including a hearing" because we believe the Council could remand an escalated case to an ALJ or attorney adjudicator for further proceedings, but if the Council ordered that a hearing be conducted, the case would need to be remanded to an ALJ. We are not proposing any corresponding changes to § 423.2108 because escalation is not available for Part D coverage appeals.

We are also proposing in §§ 405.1108(b) and 423.2108(b), to provide that the dismissal for which Council review may be requested is a dismissal of a request for a hearing, because as discussed in section III.A.3.x above, proposed §§ 405.1054(b) and 423.2054(b) would provide that a dismissal of a request for a review of a QIC or IRE dismissal of a request for reconsideration is binding and not subject to further review. Finally, we are proposing to replace all remaining references in §§ 405.1108 and 423.2108 to "ALJ" with "ALJ or attorney adjudicator" and "ALJ's" with "ALJ's or attorney adjudicator's" to further provide that the Council's actions with respect to a request for review or escalation are the same for cases that were decided by or pending before an ALJ or an attorney adjudicator.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Council actions when request for review or escalation is filed" at the beginning of your comment.

e. Council Reviews on Its Own Motion (§§ 405.1110 and 423.2110)

Current §§ 405.1110 and 423.2110 discuss Council reviews on its own motion. Current §§ 405.1110(a) and 423.2110(a) state the general rule that the Council may decide on its own motion to review a decision or dismissal issued by an ALJ, and CMS or its contractor, including the IRE, may refer a case to the Council within 60 calendar days after the date of the ALJ's decision or dismissal (for § 405.1110(a)) or after the ALJ's written decision or dismissal is issued (for § 423.2110(a)). Current §§ 405.1110(b) and 423.2110(b) provide the standards for CMS or its contractors to refer ALJ decisions and dismissals to the Council for potential review under the Council's authority to review ALJ decisions and dismissals on the Council's own motion, and require that a copy of a referral to the Council be sent to the ALJ whose decision or dismissal was referred, among others. Current §§ 405.1110(c) and 423.2110(c) explain the standards of review used by the Council in reviewing the ALJ's action. Current §§ 405.1110(d) and 423.2110(d) explain the actions the Council may take, including remanding the case to the ALJ for further proceedings, and state that if the Council does not act on a referral within 90 calendar days after receipt of the referral (unless the 90 calendar day period has been extended as provided in the respective subpart), the ALJ's decision or dismissal is binding (§ 405.1110(d) further specifies that the decision or dismissal is binding on the parties to the decision).

We are proposing at §§ 405.1110 and 423.2110 to replace each instance of "at the ALJ level" with "at the OMHA level" and "ALJ proceedings" with "OMHA proceedings". We believe the standards for referral to the Council by CMS or its contractor would be the same regardless of whether the case was decided by an ALJ or an attorney adjudicator, and that "at the OMHA level" and "OMHA proceedings" would reduce confusion in situations where the case was decided by an attorney adjudicator. We are proposing at § 405.1110(b)(2) to replace the references to current § 405.1052(b) with references to § 405.1052(d) to reflect the structure of proposed § 405.1052, and are also proposing to revise §§ 405.1110(b)(2) and 423.2110(b)(2)(ii) to state that CMS (in § 405.1110(b)(2)) or CMS or the IRE (in § 423.2110(b)(2)(ii)) sends a copy of its referral to the OMHA Chief ALJ. The current requirement to send a copy of the referral to the ALJ is helpful in allowing OMHA ALJs to review the positions that CMS is advocating before the Council, but at times has caused confusion as to whether the ALJ should respond to the referral (there is no current provision that allows the Council to consider a statement in response to the referral). In addition, the proposed revision would allow OMHA to collect information on referrals, assess whether training or policy clarifications for OMHA adjudicators are necessary, and disseminate the referral to the appropriate ALJ or attorney adjudicator for his or her information. We are also proposing at § 405.1110(b)(2) to replace "all other parties to the ALJ's decision" with "all other parties to the ALJ's or attorney adjudicator's action" and at § 405.1110(d) to replace "ALJ decision" with "ALJ or attorney adjudicator action" to encompass both decisions and dismissals issued by an ALJ or an attorney adjudicator, as proposed in section II.B above. We believe that parties to an ALJ's dismissal or an attorney adjudicator's decision or dismissal have the same right to receive a copy of another party's written exceptions to an agency referral as the parties to an ALJ's decision, and that an ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the action. We are proposing to replace each remaining instance in §§ 405.1110 and 423.2110 of "ALJ" with "ALJ or attorney adjudicator," "ALJ's decision or dismissal" with "ALJ's or attorney adjudicator's decision or dismissal," "ALJ's decision" with "ALJ's or attorney adjudicator's decision or dismissal," and "ALJ's action" with "ALJ's or attorney adjudicator's action." These proposed revisions would provide that the sections apply to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B, and therefore CMS and its contractors would have the same right to refer attorney adjudicator decisions and dismissals to the Council, and the Council would have the authority to take the same actions and have the same obligations in deciding whether to review an attorney adjudicator's decision or dismissal on its own motion.

Finally, we are proposing at § 423.2110(b)(1) to replace "material to the outcome of the claim" with "material to the outcome of the appeal" because unlike Part A and Part B, no "claim" is submitted for drug coverage under Part D.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Council reviews on its own motion" at the beginning of your comment.

f. Content of Request for Review (§§ 405.1112 and 423.2112)

Current §§ 405.1112 and 423.2112 discuss the content of a request for Council review. Current § 405.1112(a) requires a request for Council review to contain the date of the ALJ's decision or dismissal order, if any, among other information. Current § 423.2112(a)(1) states that the request for Council review must be filed with the entity specified in the notice of the ALJ's action. Current §§ 405.1112(b) and 423.2112(b) state that the request for review must identify the parts of the ALJ action with which the party or enrollee, respectively, requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dismissal, or other determination being appealed. Current § 405.1112(b) provides an example that if the party requesting review believes that the ALJ's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority. Current §§ 405.1112(c) and 423.2112(c) state that the Council will limit its review of an ALJ's action to those exceptions raised by the party or enrollee, respectively, in the request for review, unless the appellant is an unrepresented beneficiary or the enrollee is unrepresented. We are proposing at §§ 405.1112 and 423.2112 to replace "ALJ's decision or dismissal" with "ALJ's or attorney adjudicator's decision or dismissal," "ALJ action" with "ALJ or attorney adjudicator's action," "ALJ's action" with "ALJ's or attorney adjudicator's action." These proposed revisions would provide that the sections apply to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B, and therefore information on the attorney adjudicator's decision and dismissal must be included in the request for Council review, and the scope of the Council's review would be the same as for an ALJ's decision or dismissal.

Current § 405.1112(a) states that a request for Council review must be filed with the Council or appropriate ALJ hearing office. However, this provision may cause confusion when read with current § 405.1106(a), which states that a request for review must be filed with the entity specified in the notice of the ALJ's action. In practice, OMHA notices of decision and dismissal provide comprehensive appeal instructions directing requests for Council review to be filed directly with the Council, and provide address and other contact information for the Council. Therefore, we are proposing to revise § 405.1112(a) to state that the request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action, which would to align § 405.1112(a) with current § 405.1106(a), and reaffirm that a request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action.

Current § 405.1112(a) also states that the written request for review must include the hearing office in which the appellant's request for hearing is pending if a party is requesting escalation from an ALJ to the Council. In light of the proposed revisions to the escalation process discussed in section III.A.3.h.i above, we are proposing to remove this requirement from § 405.1112(a) because proposed § 405.1016 would provide that a request for escalation is filed with OMHA. In accordance with proposed § 405.1016, if the request for escalation meets the requirements of § 405.1016(f)(1) and a decision, dismissal, or remand cannot be issued within 5 calendar days after OMHA receives the request, the appeal would be forwarded to the Council.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Content of request for review" at the beginning of your comment.

g. Dismissal of Request for Review (§§ 405.1114 and 423.2114)

We are proposing at § 405.1114(c)(3) to replace "ALJ hearing" with "ALJ's or attorney adjudicator's action." This proposed revision would provide that the paragraph applies to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B, and therefore a valid and timely request for Council review filed by another party to an attorney adjudicator's decision or dismissal would preclude dismissal of a request for Council review under § 405.1114(c). We are not proposing any corresponding changes to § 423.1114 because there is no provision equivalent to current § 405.1114(c)(3).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Dismissal of request for review" at the beginning of your comment.

h. Effect of Dismissal of Request for Council Review or Request for Hearing (§§ 405.1116 and 423.2116)

Current §§ 405.1116 and 423.2116 describe the effect of a dismissal by the Council of a request for Council review or a request for hearing. We are proposing to replace "ALJ" with "ALJ or attorney adjudicator" to provide that the denial of a request for Council review of a dismissal issued by an attorney adjudicator is binding and not subject to judicial review in the same manner as the denial of a request for Council review of a dismissal issued by an ALJ. We believe the Council's denial of a request to review an attorney adjudicator's dismissal would be subject to the same general rules described in sections III.A.3.c and III.A.3.x above pertaining to reviews of dismissals at the next adjudicative level, and that further review of the attorney adjudicator's dismissal in Federal district court would be unavailable.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Effect of dismissal of request for Council review or request for hearing" at the beginning of your comment.

i. Obtaining Evidence From the Council (§§ 405.1118 and 423.2118)

Current §§ 405.1118 and 423.2118 provide that a party or an enrollee, respectively, may request and receive a copy of all or part of the record of the ALJ hearing. We are proposing to replace "ALJ hearing" with "ALJ's or attorney adjudicator's action." This proposed revision would provide that a party to an attorney adjudicator action, or to an ALJ decision that was issued without a hearing, may request and receive a copy of all or part of the record to the same extent as a party to an ALJ hearing. We are also proposing to replace the reference to an "exhibits list" with a reference to "any index of the administrative record" to provide greater flexibility in developing a consistent structure for the administrative record. In addition, we are proposing at § 405.1118 to replace the reference to a "tape" of the oral proceeding with an "audio recording" of the oral proceeding because tapes are no longer used and a more general reference would accommodate future changes in recording formats. We are proposing a parallel revision to § 423.2118 to replace the reference to a "CD" of the oral proceeding with an "audio recording" of the oral proceeding.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Obtaining evidence from the Council" at the beginning of your comment.

j. What Evidence May Be Submitted to the Council (§§ 405.1122 and 423.2122)

Current §§ 405.1122 and 423.2122 describe the evidence that may be submitted to and considered by the Council, the process the Council follows in issuing subpoenas, the reviewability of Council subpoena rulings, and the process for seeking enforcement of subpoenas. Current § 405.1122(a)(1) provides that the Council will limit its review of the evidence to the evidence contained in the record of the proceedings before the ALJ, unless the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level. We are proposing at § 405.1122(a) introductory text and (a)(1) to replace each instance of "ALJ's decision" with "ALJ's or attorney adjudicator's decision," "before the ALJ" with "before the ALJ or attorney adjudicator," and "the ALJ level" with "the OMHA level." We believe the standard for review of evidence at the Council level would be the same regardless of whether the case was decided by an ALJ or attorney adjudicator, as proposed in section II.B above, at the OMHA level. We are also proposing corresponding revisions to § 423.2122(a) introductory text and (a)(1). Also, to help ensure it is clear that the exception for evidence related to new issues raised at the OMHA level is not limited to proceedings in which a hearing before an ALJ was conducted, we are proposing at §§ 405.1122(a)(1) and § 423.2122(a)(1) to replace "hearing decision" with "ALJ's or attorney adjudicator's decision." Current § 405.1122(a)(2) provides that if the Council determines that additional evidence is needed to resolve the issues in the case, and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ to obtain the evidence and issue a new decision. For the reasons described above, we are proposing at § 405.1122(a)(2) to replace "ALJ" with "ALJ or attorney adjudicator" and "hearing record" with "administrative record," along with corresponding revisions to § 423.2122(a)(2). Current § 405.1122(b)(1) describes the evidence that may be considered by the Council when a case is escalated from the ALJ level. For the reasons described above, we are proposing to replace "ALJ level" with "OMHA level." We are not proposing any corresponding changes to § 423.2122 because escalation is not available for Part D coverage appeals. Finally, we are proposing to replace all remaining instances of "ALJ" in § 405.1122(b)(1), (b)(2), (c)(2), (c)(3) introductory text, (c)(3)(i), and (c)(3)(ii) with "ALJ or attorney adjudicator," as we believe the Council's authority to consider evidence entered in the record by an attorney adjudicator and to remand a case to an attorney adjudicator for consideration of new evidence would be the same as the Council's current authority to consider evidence entered in the record by an ALJ and remand a case to an ALJ. We are not proposing any corresponding changes to § 423.2122 because there are no remaining references to "ALJ."

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "What evidence may be submitted to the Council" at the beginning of your comment.

k. Case Remanded by the Council (§§ 405.1126 and 423.2126)

Current §§ 405.1126(a) and (b) explain the Council's remand authority. We are proposing to replace each instance of "ALJ" with "ALJ or attorney adjudicator" to provide that the Council may remand a case in which additional evidence is needed or additional action is required by the ALJ or attorney adjudicator, as proposed in section II.B above. Proposed § 405.1126(b) would also provide that an ALJ or attorney adjudicator would take any action that is ordered by the Council, and may take any additional action that is not inconsistent with the Council's remand order. We believe it is necessary for the Council to have the same authority to remand an attorney adjudicator's decision to the attorney adjudicator as the Council currently has to remand an ALJ's decision to the ALJ, and that the attorney adjudicator's actions with respect to the remanded case should be subject to the same requirements as an ALJ's actions under the current provisions. We are also proposing corresponding revisions to § 423.2126(a)(1) and (a)(2). Current §§ 405.1126(c) and (d) describe the procedures that apply when the Council receives a recommended decision from the ALJ, including the right of the parties to file briefs or other written statements with the Council. Because we are proposing in § 405.1126(a) for the Council to have the same authority to order an attorney adjudicator to issue a recommended decision on remand as the Council currently has to order an ALJ to issue a recommended decision, we are also proposing at § 405.1126(c) and (d) to replace "ALJ" with "ALJ or attorney adjudicator" to provide that the provisions apply to attorney adjudicators to the same extent as the provisions apply to ALJs, along with corresponding revisions to § 423.2126(a)(3) and (a)(4). Finally, current § 405.1126(e)(2) provides that if the Council determines more evidence is required after receiving a recommended decision, the Council may again remand the case to an ALJ for further development and another decision or recommended decision. Because we believe the Council should have the same authority to remand a case to an attorney adjudicator following receipt of a recommended decision, we are proposing at § 405.1126(e)(2) to replace "ALJ" with "ALJ or attorney adjudicator," along with a corresponding revision to § 423.2126(a)(5)(ii), and to insert "if applicable" after rehearing because a rehearing may not be applicable in every circumstance (for example, where an attorney adjudicator issued a recommended decision and the Council does not remand with instructions to transfer the appeal to an ALJ for a hearing).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Case remanded by the Council" at the beginning of your comment.

l. Action of the Council (§§ 405.1128 and 423.2128)

Current §§ 405.1128 and 423.2128 explain the actions the Council may take after reviewing the administrative record and any additional evidence (subject to the limitations on Council consideration of additional evidence). We are proposing at §§ 405.1128(a) and 423.2128(a) to replace "ALJ" with "ALJ or attorney adjudicator," which would provide that the Council may make a decision or remand a case to an ALJ or to an attorney adjudicator (as proposed in section II.B above). We believe the Council should have the same authority to remand a case to an attorney adjudicator as the Council currently has to remand a case to an ALJ. Also, to help ensure there is no confusion that Council actions are not limited to proceedings in which a hearing before an ALJ was conducted, we are proposing at §§ 405.1128(b) and 423.2128(b) to replace "the ALJ hearing decision" with "the ALJ's or attorney adjudicator's decision."

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Action of the Council" at the beginning of your comment.

m. Request for Escalation to Federal Court (§ 405.1132)

Current § 405.1132 explains the process for an appellant to seek escalation of an appeal (other than an appeal of an ALJ dismissal) from the Council to Federal district court if the Council does not issue a decision or dismissal or remand the case to an ALJ within the adjudication time frame specified in § 405.1100, or as extended as provided in subpart I. We are proposing at § 405.1132 to replace each instance of "ALJ" with "ALJ or attorney adjudicator." These revisions would provide that the appellant may request that escalation of a case, other than a dismissal issued by an ALJ or attorney adjudicator, as proposed in section II.B above to Federal district court if the Council is unable to issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator within an applicable adjudication time frame, and that appellants may file an action in Federal district court if the Council is not able to issue a decision, dismissal, or remand to the ALJ or attorney adjudicator within 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period. We are not proposing any corresponding changes to part 423, subpart U, as there is no equivalent provision because there are no escalation rights for Part D coverage appeals.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Request for escalation to Federal court" at the beginning of your comment.

n. Judicial Review (§§ 405.1136, 423.1976, and 423.2136)

Current §§ 405.1136, 423.1976, and 423.2136 set forth the right to file a request for judicial review in Federal district court of a Council decision (or of an ALJ's decision if the Council declines review as provided in § 423.1976(a)(1)). Current § 405.1136 also provides that judicial review in Federal district court may be requested if the Council is unable to issue a decision, dismissal, or remand within the applicable time frame following an appellant's request for escalation. In addition, current §§ 405.1136 and 423.2136 specify the requirements and procedures for filing a request for judicial review, the Federal district court in which such actions must be filed, and describe the standard of review. We are proposing at §§ 405.1136, 423.1976, and 423.2136 to replace each instance of "ALJ" with "ALJ or attorney adjudicator," and "ALJ's" with "ALJ's or attorney adjudicator's" to help ensure that there is no confusion that appellants may file a request for judicial review in Federal district court of actions made by an attorney adjudicator, as proposed in section II.B above (or by the Council following an action by an attorney adjudicator), to the same extent that judicial review is available for ALJ actions (or Council actions following an action by an ALJ).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Judicial review" at the beginning of your comment.

o. Case Remanded by a Federal Court (§§ 405.1138 and 423.2138)

Current §§ 405.1138 and 423.2138 set forth the actions the Council may take when a Federal district court remands a case to the Secretary for further consideration. We are proposing at §§ 405.1138 and 423.2138, and 405.1140 and 423.2140 to replace "ALJ" with "ALJ or attorney adjudicator" to provide that when a case is remanded by a Federal district court for further consideration by the Secretary, the Council may remand the case to an ALJ or attorney adjudicator (as proposed in section II.B above), to issue a decision, take other action, or return the case to the Council with a recommended decision.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Case remanded by a Federal court" at the beginning of your comment.

p. Council Review of ALJ Decision in a Case Remanded by a Federal District Court (§§ 405.1140 and 423.2140)

Current §§ 405.1140 and 423.2140 set forth the procedures that apply when a case is remanded to the Secretary for further consideration, and the Council subsequently remands the case to an ALJ, including the procedures for the Council to assume jurisdiction following the decision of the ALJ on its own initiative or upon receipt of written exceptions from a party or the enrollee. We are proposing to replace each instance of "ALJ" throughout §§ 405.1140 and 423.2140 with "ALJ or attorney adjudicator" and to replace the reference to "ALJ's" at §§ 405.1140(d) and 423.2140(d) with "ALJ's or attorney adjudicator's." These revisions would provide that the Council may remand these cases to the ALJ or attorney adjudicator, as proposed in section II.B above, following remand from a Federal district court, and that the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand unless the Council assumes jurisdiction. These revisions would further apply the rules set forth in this section to cases reviewed by an attorney adjudicator as well as an ALJ. As described above in relation to the Council's general remand authority under §§ 405.1126 and 423.2126, we believe it is necessary for the Council to have the same authority to remand an attorney adjudicator's decision to the attorney adjudicator as the Council currently has to remand an ALJ's decision to the ALJ, and that would include cases that are remanded by a Federal district court to the Secretary for further consideration.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Council review of ALJ decision in a case remanded by a Federal district court" at the beginning of your comment.

B. Part 405, Subpart J Expedited Reconsiderations (§ 405.1204)

In accordance with section 1869(b)(1)(F) of the Act, current § 405.1204 provides for expedited QIC reconsiderations of certain QIO determinations related to provider-initiated terminations of Medicare-covered services and beneficiary discharges from a provider's facility. Current § 405.1204(c)(4)(iii) explains that the QIC's initial notification may be done by telephone followed by a written notice that includes information about the beneficiary's right to appeal the QIC's reconsideration decision to an ALJ, and current § 405.1204(c)(5) provides that if the QIC does not issue a decision within 72 hours of receipt of the request for a reconsideration, the case can be escalated to the "ALJ hearing level." For consistency with part 405, subpart I, and to explain the rules that apply to an ALJ hearing, we are proposing at § 405.1204(c)(4)(iii) and (c)(5) to amend these references to convey that a QIC reconsideration can be appealed to, or a request for a QIC reconsideration can be escalated to OMHA for an ALJ hearing in accordance with part 405, subpart I. We believe these revisions would explain where a request for an ALJ hearing is directed from a subpart J proceeding, and the rules that would be applied to the request for an ALJ hearing following the QIC's reconsideration or escalation of the request for a QIC reconsideration.

Current § 405.1204(c)(5) states that the beneficiary has a right to escalate a request for a QIC reconsideration if the amount remaining in controversy after the QIO determination is $100 or more. However, this is inconsistent with the amount in controversy specified in section 1869(b)(1)(E) of the Act. We are proposing to revise § 405.1204(c)(5) to provide that there is a right to escalate a request for a QIC reconsideration if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under § 405.1006. We believe that this is more consistent with section 1869(b)(1)(E) of the Act, which provides that a hearing by the Secretary shall not be available to an individual if the amount in controversy is less than $100, as adjusted annually after 2004, which is implemented in § 405.1006, and would bring consistency to the amounts in controversy required for an escalation under subpart J and subpart I.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Part 405, subpart J expedited reconsiderations" at the beginning of your comment.

C. Part 422, Subpart M

1. General Provisions (§ 422.562)

Current § 422.562(c)(1)(ii) states that if an enrollee receives immediate QIO review of a determination of non-coverage of inpatient hospital care, the QIO review decision is subject only to the appeal procedures set forth in parts 476 and 478 of title 42, chapter IV. However, we believe this provision is an outdated reference that has been superseded by current § 422.622, which provides for requesting immediate QIO review of the decision to discharge an enrollee from an inpatient hospital setting and appeals of that review as described under part 422, subpart M. The regulatory provisions at § 422.622 describe the processes for QIO review of the decision to discharge an MA enrollee from the inpatient hospital setting. Section 422.622 also explains the availability of other appeals processes if the enrollee does not meet the deadline for an immediate QIO review of the discharge decision. These part 422, subpart M provisions govern the review processes for MA enrollees disputing discharge from an inpatient hospital setting. As noted above, we believe the references to the procedures in parts 476 and 478 at § 422.562(c)(1)(ii) are obsolete. Therefore, we are proposing to delete § 422.562(c)(1) to remove the outdated reference in current § 422.562(c)(1)(ii) and consolidate current (c)(1) and (c)(1)(i) into proposed (c)(1). We also note that changes to § 422.562(d) are proposed and discussed in section II.C, above.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "General provisions" at the beginning of your comment.

2. Notice of Reconsidered Determination by the Independent Entity (§ 422.594)

Current § 422.594(b)(2) requires the notice of the reconsideration determination by an IRE to inform the parties of their right to an ALJ hearing if the amount in controversy is $100 or more, if the determination is adverse (does not completely reverse the MAO's adverse organization determination). We are proposing at § 422.594(b)(2) to amend this requirement so that the notice informs the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of § 422.600, which in turn refers to the part 405 computation of the amount in controversy. We believe this would increase accuracy in conveying when a party has a right to an ALJ hearing, and would be more consistent with section 1852(g)(5) of the Act, which provides that a hearing by the Secretary shall not be available to an individual if the amount in controversy is less than $100, as adjusted annually in accordance with section 1869(b)(1)(E)(iii) of the Act, which is implemented in part 405 at § 405.1006. We discuss proposed changes to § 405.1006 in section III.A.3.d above.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Notice of reconsidered determination by the independent entity" at the beginning of your comment.

3. Request for an ALJ Hearing (§ 422.602)

Current § 422.602(b) provides that a party must file a request for an ALJ hearing within 60 days of the date of the notice of the IRE's reconsidered determination. However, in similar appeals brought under Medicare Part A and Part B at § 405.1002, and Part D at § 423.2002, a request for an ALJ hearing must be filed within 60 calendar days of receipt of a notice of reconsideration. We are proposing at § 422.602(b)(1) to align the part 422 time frame for filing a request for an ALJ hearing with provisions for similar appeals under Medicare Part A and Part B, and Part D. As proposed, a request for an ALJ hearing would be required to be filed within 60 calendar days of receiving the notice of a reconsidered determination, except when the time frame is extended by an ALJ or, as proposed, attorney adjudicator, as provided in part 405. To provide consistency for when a notice of a reconsidered determination is presumed to have been received, we are proposing at § 422.602(b)(2) that the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary, which is the same presumption that is applied to similar appeals under Medicare Part A and Part B at § 405.1002, and Part D at § 423.2002.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Request for an ALJ hearing" at the beginning of your comment.

4. Medicare Appeals Council (Council) Review (§ 422.608)

Current § 422.608 provides that any party to the hearing, including the MAO, who is dissatisfied with the ALJ hearing decision may request that the Council review the ALJ's decision or dismissal. We believe that the reference to a hearing, hearing decision, then decision or dismissal may cause confusion regarding a party's right to request Council review. We are proposing at § 422.608 that any party to the ALJ's or, as proposed in section II.B above, attorney adjudicator's decision or dismissal, including the MAO, who is dissatisfied with the decision or dismissal, may request that the Council review the decision or dismissal. We believe this would resolve any potential confusion regarding a party's right to request Council review of a decision when a hearing was not conducted, and a dismissal of a request for hearing, and provide that the section applies to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B. Therefore, proposed § 422.608 would provide that a request for Council review may be filed by a party if he or she is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Medicare Appeals Council (Council) review" at the beginning of your comment. We discuss other proposed changes to § 422.608 in section II.D above.

5. Judicial Review (§ 422.612)

Current § 422.612 provides the circumstances under which a party may request judicial review of an ALJ or Council decision, and directs appellants to the procedures in part 405 for filing a request for judicial review. We are proposing at § 422.612(a) to replace each instance of "ALJ's" with "ALJ's or attorney adjudicator's". Thus, as provided in § 422.612(a), appellants would be able to file a request for judicial review in Federal district court of actions made by an attorney adjudicator, as proposed in section II.B above (or by the Council following an action by an attorney adjudicator), to the same extent that judicial review is available under § 412.622(a) for ALJ actions (or Council actions following an action by an ALJ).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Judicial review" at the beginning of your comment.

6. Reopening and Revising Determinations and Decisions (§ 422.616)

Current § 422.616(a) provides that the determination or decision of an MA organization, independent entity, ALJ, or the Council that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, subject to the rules in part 405. We are proposing at § 422.616(a) to replace "ALJ" with "ALJ or attorney adjudicator." As described in section III.A.2.l above with respect to §§ 405.980, 405.982, 405.984, 423.1980, 423.1982, and 423.1984, we believe it is necessary for an attorney adjudicator to have the authority to reopen the attorney adjudicator's decision on the same bases as an ALJ may reopen the ALJ's decision under the current rules, and the action should be subject to the same limitations and requirements, and have the same effects as an ALJ's action under these provisions.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Reopening and revising determinations and decisions" at the beginning of your comment.

7. How an MA Organization Must Effectuate Standard Reconsideration Determinations and Decisions, and Expedited Reconsidered Determinations (§§ 422.618 and 422.619)

Current § 422.618(c)(1) and (c)(2) provide instructions for effectuation of decisions issued by an ALJ, or at a higher level of appeal, that reverse an IRE's decision on a standard reconsidered determination or decision. We are proposing to replace "ALJ" with "ALJ or attorney adjudicator" at § 422.618(c)(1) and to make corresponding changes to § 422.619(c)(1) for decisions that reverse an IRE's decision on an expedited reconsidered determination or decision. We believe the process for effectuating the decision of an attorney adjudicator, as proposed in section II.B above, should be the same as the process for effectuating the decision of an ALJ.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "How an MA organization must effectuate standard reconsideration determinations and decisions, and expedited reconsidered determinations" at the beginning of your comment.

8. Requesting Immediate QIO Review of the Decision to Discharge From the Inpatient Hospital and Fast-Track Appeals of Service Terminations to Independent Review Entities (IREs) (§§ 422.622 and 422.626).

In accordance with section 1852(g)(3) and (g)(4) of the Act, current §§ 422.622 and 422.626 provide for reviews of QIO determinations and expedited IRE reconsiderations of certain QIO determinations related to terminations of covered provider services furnished by home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs) to a Medicare Advantage enrollee, and Medicare Advantage enrollee discharges from an inpatient hospital. Current § 422.622(g) provides that if an enrollee is still an inpatient in the hospital after a QIO determination reviewing a provider discharge from a hospital, the enrollee may request an IRE reconsideration of the QIO determination in accordance with § 422.626(g); and if an enrollee is no longer an inpatient in the hospital, the enrollee may appeal the QIO determination to an ALJ. Current § 422.626(g)(3) provides that if the IRE reaffirms its decision to terminate covered provider services furnished by a HHA, SNF, or CORF in whole or in part, the enrollee may appeal the IRE's reconsidered determination to an ALJ. We are proposing at §§ 422.622(g)(2) and 422.626(g)(3) to amend these references to provide that the appeal is made to OMHA for an ALJ hearing. We believe these revisions would clarify where a request for an ALJ hearing is directed.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Requesting immediate QIO review of the decision to discharge from the inpatient hospital and fast-track appeals of service terminations to independent review entities (IREs)" at the beginning of your comment.

D. Part 478, Subpart B

1. Applicability and Beneficiary's Right to a Hearing (§§ 478.14 and 478.40)

Current § 478.14(c)(2) explains that for the purposes of part 478 reconsideration and appeals, limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act, and initial determinations under section 1879 of the Act and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G for determinations under Medicare Part A, and part 405, subpart H for determinations under Medicare Part B. In addition, current § 478.40 states that an ALJ hearing may be obtained from the SSA Office of Hearings and Appeals, and the provisions of subpart G of 42 CFR part 405 apply unless they are inconsistent with the specific provisions of subpart B of 42 CFR part 478. These references are outdated. Since §§ 478.14 and 478.40 were last updated in 1999, section 931 of the MMA transferred responsibility for the ALJ hearing function from SSA to HHS, and HHS established OMHA in 2005, to administer the ALJ hearing function, including ALJ hearings conducted under titles XI and XVIII of the Social Security Act (see 70 FR 36386). In addition, BIPA and the MMA established new appeal procedures that were implemented in 2005, at 42 CFR part 405, subpart I (70 FR 11420), and the portions of subparts G and H that previously applied to part 478, subpart B appeals were removed in 2012 (77 FR 29002). Proposed §§ 478.14 and 478.40 would replace the current outdated references to part 405, subparts G and H, with references to part 405, subpart I. Proposed § 478.40 would also update the reference to the entity with responsibility for the ALJ hearing function by replacing the SSA Office of Hearings and Appeals with OMHA.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Applicability and beneficiary's right to a hearing" at the beginning of your comment.

2. Submitting a Request for a Hearing (§ 478.42)

Similar to current § 478.40, as discussed above, current § 478.42(a) has outdated references to SSA offices that are no longer involved in the Medicare claim appeals process. In addition, current § 478.42(a) permits beneficiaries to file requests for an ALJ hearing with other entities, which could cause significant delays in obtaining a hearing before an OMHA ALJ. Proposed § 478.42(a) would direct beneficiaries to file a request for an ALJ hearing with the OMHA office identified in the QIO's notice of reconsidered determination. This revision would be clearer for beneficiaries, who are provided with appeal instructions by the QIOs, and reduce delays in obtaining a hearing by an OMHA ALJ.

Current § 478.42(b) requires that a request for hearing is filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination and the date of receipt is assumed to be 5 days after the date on the notice unless there is a reasonable showing to the contrary. Current § 478.42(b) also provides that a request is considered filed on the date it is postmarked. To align part 478, subpart B with procedures for requesting an ALJ hearing under part 405, subpart I; part 422, subpart M; and part 423, subpart U, proposed § 478.42(b) would provide that the request for hearing must be filed within 60 "calendar" days of receiving notice of the QIO reconsidered determination and that the notice is presumed to be received 5 "calendar" days after the date of the notice. In addition, to further align the part 478, subpart B procedures for requesting an ALJ hearing with the other parts, proposed § 478.42(c) would amend the standard to demonstrate that notice of QIO reconsidered determination was not received within 5 calendar days by requiring "evidence" rather than the current "reasonable showing," and would also revise when a request is considered filed, from the date it is postmarked to the date it is received by OMHA. These changes would create parity with requests for hearing filed by beneficiaries and enrollees for similar services but under other parts of title 42, chapter IV.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Submitting a request for a hearing" at the beginning of your comment.

3. Determining the Amount in Controversy (§ 478.44)

Current § 478.44(a) explains how the amount in controversy for an ALJ hearing is determined in part 478, subpart B hearings. Current § 478.44(a) has outdated references to §§ 405.740 and 405.817 from part 405, subparts G and H respectively, for calculating the amount in controversy for an individual appellant or multiple appellants. In 2012, subpart G was removed and subpart H was significantly revised and no longer applies to Medicare claim appeals (77 FR 29002). To update these reference to the current part 405 rules, proposed § 478.44(a) would replace the outdated cross-references for calculating the amount in controversy with § 405.1006(d) and (e), which describe the calculation for determining the amount in controversy and the standards for aggregating claims by an individual appellant or multiple appellants. We discuss proposed changes to § 405.1006 in section III.A.3.d above.

Current § 478.44(b) and (c) explain that if an ALJ determines the amount in controversy is less than $200, the ALJ, without holding a hearing, notifies the parties to the hearing, and if a request for hearing is dismissed because the amount in controversy is not met, a notice will be sent to the parties to the hearing. However, when a request for hearing is dismissed because the amount in controversy is not met, no hearing is conducted and the parties are parties to the proceedings regardless of whether a hearing was conducted. To prevent potential confusion, proposed § 478.44(b) and (c) would replace "parties to the hearing" with "parties" so it is understood that they are parties regardless of whether a hearing is conducted. Because an attorney adjudicator would have to determine whether appeals assigned to him or her, as proposed in section II.B above, meet the amount in controversy requirement, we also propose at § 478.44(a) and (b) that an attorney adjudicator may determine that the amount in controversy, and may determine the amount in controversy is less than $200 and notify the parties to submit additional evidence to prove that the amount in controversy is at least $200. However, because we are not proposing that an attorney adjudicator can dismiss a request for an ALJ hearing because the amount in controversy is not met, proposed § 478.44(c) provides that an ALJ would dismiss a request if at the end of the 15-day period to submit additional evidence to prove that the amount in controversy is at least $200, the ALJ determines that the amount in controversy is less than $200.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Determining the amount in controversy" at the beginning of your comment.

4. Medicare Appeals Council and Judicial Review (§ 478.46)

Current § 478.46(a) states that the Council will review an ALJ's hearing decision or dismissal under the same circumstances as those set forth at 20 CFR 404.970, which is now an outdated reference to SSA Appeals Council procedures for Council review. We are proposing at § 478.46(a) to replace the outdated reference to 20 CFR 404.970 with references to current §§ 405.1102 ("Request for Council review when ALJ or attorney adjudicator issued a decision or dismissal") and 405.1110 ("Council reviews on its own motion"). In addition, we are proposing in § 478.46(a) and (b) to replace "hearing decision" with "decision," and "ALJ" with "ALJ or attorney adjudicator" because hearings are not always conducted and a decision can generally be appealed regardless of whether a hearing was conducted, and attorney adjudicators may issue decisions or dismissals for which Council review may be requested, as proposed in section II.B above.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Medicare Appeals Council and judicial review" at the beginning of your comment.

5. Reopening and Revision of a Reconsidered Determination or a Decision (§ 478.48)

The title of current § 478.48 references reopenings and revisions of reconsidered determinations and hearing decisions, and current § 478.48 has an outdated reference to subpart G of 42 CFR part 405 for the procedures for reopening a decision by an ALJ or the Departmental Appeals Board.

We are proposing to revise the title of § 478.48 to replace "hearing decision" with "decision," and in proposed paragraphs (b) and (c) to replace "ALJ" with "ALJ or attorney adjudicator" so the provision is understood to apply to decisions by ALJs, regardless of whether a hearing was conducted, or, as proposed in section II.B above, attorney adjudicators, as well as review decisions, which are conducted by the Medicare Appeals Council at the Departmental Appeals Board. We also propose at § 478.48(b) to replace the outdated reference to § 405.750(b), which was part of the now removed part 405, subpart G (77 FR 29016 through 29018), with § 405.980, which is the current part 405, subpart I reopening provision.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption "Reopening and revision of a reconsidered determination or a decision" at the beginning of your comment.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The PRA exempts most of the information collection activities referenced in this proposed rule. In particular, the implementing regulations of the PRA at 5 CFR 1320.4 exclude collection activities during the conduct of a civil action to which the United States or any official or agency thereof is a party. Civil actions include administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment, or MAO organization determination or Part D plan sponsor coverage determination. However, one requirement contained in this proposed rule is subject to the PRA because the burden is imposed prior to an administrative action or denial of payment. This requirement is discussed below.

In summary, we are proposing at § 405.910 that when a provider or supplier is the party appointing a representative, the appointment of representation would include the Medicare National Provider Identifier (NPI) of the provider or supplier that furnished the item of service. Although this is a new regulatory requirement, the current Medicare Claims Processing Manual already states that the NPI should be included when a provider or supplier appoints a representative. The standardized form for appointing a representative, Form CMS–1696, currently provides a space for the information in question. Importantly, this form is currently approved under OMB control number 0938–0950 and expires June 30, 2018.

The burden associated with this requirement is the time and effort of an individual or entity who is a provider or supplier to prepare an appointment of representation containing the NPI. As stated earlier, this requirement and the related burden are subject to the PRA; however, because we believe that this information is already routinely being collected, we estimate there would be no additional burden for completing an appointment of representative in accordance with proposed 405.910.

If you wish to view the standardized form and the supporting documentation, you can download a copy from the CMS Web site at *https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-list.html.*

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above.

We are inviting public comment on the burden associated with these information collection requirements.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that the effect of this proposed rule does not reach this economic threshold and thus is not considered a major rule. As detailed above, this proposed rule would only make minimal changes to the existing Medicare appeals procedures for claims for benefits under or entitlement to the original Medicare programs, and coverage of items, services, and drugs under the Medicare Advantage and voluntary Medicare prescription drug programs. Thus, this proposed rule would have negligible financial impact on beneficiaries and enrollees, providers or suppliers, Medicare contractors, MAOs, and Part D plan sponsors, but would derive benefits to the program and appellants.

HHS recognizes that the current appeals backlog is a matter of great significance, and it has made it a priority to adopt measures that are designed to reduce the backlog and improve the overall Medicare appeals process moving forward. To that end, HHS has initiated a series of measures, including this proposed regulation, that are aimed at both reducing the backlog and creating a more efficient Medicare appeals system.

We believe the changes proposed in this regulation will help address the Medicare appeals backlog and create efficiencies at the ALJ level of appeal by allowing OMHA to reassign a portion of workload to non-ALJ adjudicators, reduce appeals of low-value claims, and reduce procedural ambiguities that result in unproductive efforts at OMHA and unnecessary appeals to the Medicare Appeals Council. In addition, the other proposed changes, including precedential decisions and generally limiting CMS and CMS contractor participation or party status at the OMHA level unless the ALJ determines participation by additional entities is necessary for a full examination of the matters at issue (as provided in proposed §§ 405.1010(d) and 405.1012(d)), will collectively make the ALJ hearing process more efficient through streamlined and standardized procedures and more consistent decisions, and reduce appeals to the Medicare Appeals Council.

In particular, we are able to estimate the impact from two of the proposed modifications: proposals to expand the pool of adjudicators and the modifications to calculating the amount in controversy (AIC) required for an ALJ hearing. Based on FY 2015, and an assumption that future years are similar to FY 2015, we estimate that the proposals to expand the pool of adjudicators at OMHA could redirect approximately 23,650 appeals per year to attorney adjudicators to process these appeals at a lower cost than would be required if only ALJs were used to address the same workload. If the number of requests for hearing, waivers of oral hearing, requests for review of a contractor dismissal, or appellant withdrawals of requests for hearing vary from FY 2015 in future years then the number of appeals potentially addressed by attorney adjudicators would likely also vary. Additionally, based on FY 2015 requests for an ALJ hearing, we estimate that revising the calculation methodology for the AIC required for an ALJ hearing could remove appeals related to over 2,600 Part B low-value claims per year from the ALJ hearing process, after accounting for the likelihood of appellants aggregating claims to meet the AIC. We also note that appeals filed by Medicare beneficiaries, and Medicare Advantage and Part D prescription drug plan enrollees would be minimally impacted because they often appeal claim or coverage denials for which they are financially responsible, and for which we would use the existing AIC calculation methodology. We note that this analysis is limited by the use of only one fiscal year's worth of data, and that there is uncertainty in this estimate as the number of appeals that would fall under the revised AIC calculation may vary from year to year.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule would not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

For purposes of the RFA, most providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. In addition, a number of MAOs and Part D plan sponsors (insurers) are small entities due to their nonprofit status; however, few if any meet the SBA size standard for a small insurance firm by having revenues of $38.5 million or less in any one year. Individuals and States are not included in the definition of a small entity. We have determined and we certify that this proposed rule would not have a significant economic impact on a substantial number of small entities because as noted above, this proposed rule if finalized would make only minimal changes to the existing appeals procedures. Therefore, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For proposed rules, this analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We have determined that this proposed rule would not have a significant effect on the operations of a substantial number of small rural hospitals. As noted above, this proposed rule if finalized would make only minimal changes to the existing appeals procedures and thus, would not have a significant impact on small entities or the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure in any one year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $146 million. This proposed rule would not impose spending costs on State, local, or tribal governments in the aggregate, or on the private sector in the amount of $146 million in any one year, because as noted above, this proposed rule if finalized would make only minimal changes to the existing appeals procedures.

VII. Federal Analysis

Executive Order 13132 on Federalism establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule would not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate federalism.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 478

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5).

■ 2. Section 401.109 is added to read as follows:

§ 401.109 Precedential Final Decisions of the Secretary.

(a) The Chair of the Department of Health and Human Services Departmental Appeals Board may designate a final decision of the Secretary issued by the Medicare Appeals Council in accordance with part 405, subpart I; part 422, subpart M; part 423, subpart U; or part 478, subpart B, of this chapter as precedential.

(b) Precedential decisions are made available to the public, with personally identifiable information of the beneficiary removed, and have precedential effect from the date they are made available to the public. Notice of precedential decisions is published in the **Federal Register**.

(c) Medicare Appeals Council decisions designated in accordance with paragraph (a) of this section have precedential effect and are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(d) Precedential effect, as used in this section, means that the Medicare Appeals Council's—

(1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

(2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 4. Section 405.902 is amended by adding the definitions of "Attorney Adjudicator", "Council", and "OMHA" in alphabetical order and removing the definition of "MAC" to read as follows:

§ 405.902 Definitions.

* * * * *

Attorney Adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals.

* * * * *

Council stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

* * * * *

OMHA stands for the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act.

* * * * *

■ 5. Section 405.904 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) * * *

(1) *Entitlement appeals.* The SSA makes an initial determination on an application for Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an Administrative Law Judge (ALJ) under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or an attorney adjudicator, he or she may request the Medicare Appeals Council (Council) to review the case. Following the action of the Council, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ. If the beneficiary obtains a hearing before the ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator, he or she may request the Council to review the case. If the Council reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

* * * * *

§ 405.906 [Amended]

■ 6. Section 405.906(b) introductory text is amended by—

■ a. Removing from the paragraph heading the phrase "hearing and MAC" and adding "proceedings on a request for hearing, and Council review" in its place.

■ b. Removing the phrase "hearing, and MAC review" and adding "proceedings on a request for hearing, and Council review" in its place.

§ 405.908 [Amended]

■ 7. Section 405.908 is amended by—

■ a. Removing the term "ALJ" and adding "OMHA" in its place.

■ b. Removing the term "MAC" and adding "Council" in its place.

■ 8. Section 405.910 is amended by—

■ a. Revising paragraph (c)(5).

■ b. Adding paragraph (d)(3).

■ c. Revising paragraphs (f)(1), (i)(2), and (3).

■ d. Revising paragraph (l).

■ e. Adding paragraph (m)(4).

The additions and revisions read as follows:

§ 405.910 Appointed representatives.

* * * * *

(c) * * *

(5) Identify the beneficiary's Medicare health insurance claim number when the beneficiary is the party appointing a representative, or identify the Medicare National Provider Identifier number of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative;

* * * * *

(d) * * *

(3) If an adjudication time frame applies, the time from the later of the date that a defective appointment of representative was filed or the current appeal request was filed by the prospective appointed representative, to the date when the defect was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative does not count towards the adjudication time frame.

* * * * *

(f) * * *

(1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the OMHA level are not considered proceedings before the Secretary.

* * * * *

(i) * * *

(2) *Appeals.* When a contractor, QIC, ALJ or attorney adjudicator, or the Council takes an action or issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or attorney adjudicator, or Council sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

* * * * *

(l) *Delegation of appointment by appointed representative.* (1) An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(i) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual, which contains the name of the designee and the designee's acceptance to be obligated by and comply with the requirements of representation under this subpart; and

(ii) The party accepts the designation as evidenced by a written statement signed by the party. The written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice described in paragraph (l)(1)(i) of this section so indicates.

(2) A delegation is not effective until the adjudicator receives a copy of the acceptance described in paragraph (l)(1)(ii) of this section, unless the appointed representative and designee are attorneys in the same law firm or organization, in which case the notice described in paragraph (l)(1)(i) of this section may be submitted even though the acceptance described in paragraph (l)(1)(ii) of this section is not required.

(3) A party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated is not good cause for missing a deadline or not appearing at a hearing.

(m) * * *

(4) A party's or representative's failure to notify the adjudicator that an appointment of representative has been revoked is not good cause for missing a deadline or not appearing at a hearing.

■ 9. Section 405.926 is amended by revising paragraphs (l) and (m) to read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(l) A contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, decision, or review decision.

(m) Determinations that CMS or its contractors may participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing or Council review.

* * * * *

§ 405.956 [Amended]

■ 10. Section 405.956(b)(8) is amended by removing the phrase "an ALJ hearing" and adding "the OMHA level" in its place.

■ 11. Section 405.968 is amended by revising paragraph (b)(1) to read as follows:

§ 405.968 Conduct of a reconsideration.

* * * * *

(b) * * *

(1) National coverage determinations (NCDs), CMS Rulings, Council decisions designated by the Chair of the Departmental Appeals Board as having precedential effect under § 401.109 of this chapter, and applicable laws and regulations are binding on the QIC.

* * * * *

■ 12. Section 405.970 is amended by revising the section heading and paragraphs (a) introductory text, (b), (c) introductory text, (e)(1), (e)(2)(i) and (ii) to read as follows:

§ 405.970 Timeframe for making a reconsideration following a contractor redetermination.

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration following a contractor redetermination or any additional time provided by paragraph (b) of this section, the QIC mails, or otherwise transmits to the parties at their last known addresses, written notice of—

* * * * *

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180 calendar day filing deadline made in accordance with § 405.962(b), the QIC's 60 calendar day decisionmaking timeframe begins on the date the QIC receives the late filed request for reconsideration following a contractor redetermination, or when the request for an extension that meets the requirements of § 405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration following a contractor redetermination from multiple parties, consistent with § 405.964(c), the QIC must issue a reconsideration, notice that it cannot complete its review, or dismissal within 60 calendar days for each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration following a contractor redetermination is filed, the QIC's 60 calendar day decisionmaking timeframe is extended by up to 14 calendar days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 calendar days of receiving a request for a reconsideration following a contractor redetermination, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

* * * * *

(e) * * *

(1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration following a contractor redetermination and notifies the appellant of its action consistent with § 405.972 or § 405.976.

(2) * * *

(i) Complete its reconsideration following a contractor redetermination and notify all parties of its decision consistent with § 405.972 or § 405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to OMHA.

■ 13. Section 405.972 is amended by—

■ a. Revising the section heading.

■ b. Amending paragraph (b)(3) by removing the phrase "reconsideration of a contractor's dismissal" and adding "review of a contractor's dismissal" in its place.

■ c. Amending paragraph (e) by adding the phrase "or attorney adjudicator" after the phrase "modified or reversed by an ALJ" and removing the phrase "reconsideration of a contractor's dismissal" and adding "review of a contractor's dismissal" in its place.

The revision reads as follows:

§ 405.972 Withdrawal or dismissal of a request for reconsideration or review of a contractor's dismissal of a request for redetermination.

* * * * *

■ 14. Section 405.974 is amended by—

■ a. Revising the section heading.

■ b. Amending the heading to paragraph (b) by removing the phrase "Reconsideration of contractor's" and adding "Review of a contractor's" in its place.

■ c. Amending paragraph (b)(3) by removing the word "reconsideration" and adding "review" in its place.

The revision reads as follows:

§ 405.974 Reconsideration and review of a contractor's dismissal of a request for redetermination.

* * * * *

■ 15. Section 405.976 is amended by—

■ a. Amending paragraph (b)(5)(ii) by removing the phrase "at an ALJ level, or made part of the administrative record" and adding "at the OMHA level" in its place.

■ b. Revising paragraph (b)(7) to read as follows:

§ 405.976 Notice of a reconsideration.

* * * * *

(b) * * *

(7) A statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if—

(i) The request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency; and

(ii) The reconsideration decision is partially or fully unfavorable.

* * * * *

§ 405.978 [Amended]

■ 16. Section 405.978(a) is amended by removing the phrase "An ALJ decision" and adding "An ALJ or attorney adjudicator decision" in its place.

■ 17. Section 405.980 is amended by revising the section heading and paragraphs (a)(1)(iii) and (iv), (a)(4) and (5), (d) paragraph heading, (d)(2) and (3), (e) paragraph heading, and (e)(2) and (3) to read as follows:

§ 405.980 Reopening of initial determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) * * *

(1) * * *

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

* * * * *

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(5) The contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

* * * * *

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by a QIC, ALJ or attorney adjudicator, or the Council.*

* * * * *

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 405.986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision, at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by a party.*

* * * * *

(2) A party to an ALJ or attorney adjudicator decision may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 405.986.

(3) A party to a Council review may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986.

§ 405.982 [Amended]

■ 18. Section 405.982(a) and (b) are amended by removing the phrase "ALJ, or the MAC" and adding the phrase "ALJ or attorney adjudicator, or the Council" in its place.

■ 19. Section 405.984 is amended by—

■ a. Amending paragraph (c) by removing the phrase "in accordance with § 405.1000 through § 405.1064" and adding "in accordance with § 405.1000 through § 405.1063" in its place.

■ b. Revising paragraphs (d) and (e) to read as follows:

§ 405.984 Effect of a revised determination or decision.

* * * * *

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding upon all parties unless a party files a written request for a Council review that is accepted and processed in accordance with § 405.1100 through § 405.1130.

(e) *Council review.* The revision of a Council review is binding upon all parties unless a party files a civil action in which a Federal district court accepts jurisdiction and issues a decision.

* * * * *

■ 20. Section 405.990 is amended by—

■ a. Amending paragraph (a)(2) by removing the phrase "Medicare Appeals Council (MAC)" and adding the term "Council" in its place.

■ b. Amending paragraphs (b)(1) introductory text, (b)(1)(i)(B), (b)(4), and (d)(2)(ii) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ c. Amending paragraph (b)(1)(i)(A) by removing the phrase "the ALJ has" and adding "the ALJ or attorney adjudicator has" in its place.

■ d. Amending paragraph (b)(1)(ii) by removing the phrase "to the ALJ level" and adding "to OMHA for an ALJ hearing" in its place.

■ e. Amending paragraphs (c)(3), (4), and (5) by removing the term "ALJ hearing decision" and adding "ALJ or attorney adjudicator decision" in its place.

■ h. Revising paragraph (d)(1).

■ i. Amending paragraph (d)(2)(i) by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

■ j. Amending paragraph (d)(2)(ii) by removing the term "MAC's" and adding "Council's" in its place.

■ k. Revising paragraphs (i)(1) and (2).

The revisions read as follows:

§ 405.990 Expedited access to judicial review.

* * * * *

(d) * * *

(1) *Method and place for filing request.* The requestor may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA, or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

* * * * *

(i) * * *

(1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises in writing all parties that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed, and if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

* * * * *

■ 21. Section 405.1000 is revised to read as follows:

§ 405.1000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If a party is dissatisfied with a QIC's reconsideration, or if the adjudication period specified in § 405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, CMS or its contractor may participate in the proceedings under § 405.1010, or join the hearing before an ALJ as a party under § 405.1012.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If all parties who are due a notice of hearing in accordance with § 405.1020(c) waive their right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties who are entitled to a notice of hearing in accordance with § 405.1020(c) have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide to appear.

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and there is no other party or no other party is entitled to a notice of hearing in accordance with § 405.1020(c).

(h) If more than one party timely files a request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued.

§ 405.1002 [Amended]

■ 22. Section 405.1002 is amended by—

■ a. Amending paragraph (a) introductory text by removing the phrase "may request" and adding "has a right to" in its place

■ b. Amending paragraph (a)(4) by removing the word "entity" and adding "office" in its place.

■ c. Amending paragraph (b)(1) by removing the phrase "to the ALJ level" and adding "for a hearing before an ALJ" in its place.

■ 23. Section 405.1004 is amended by—

■ a. Revising the section heading and paragraphs (a) introductory text, (a)(1) and (4), (b), and (c).

■ b. Adding paragraph (d).

The revisions and addition read as follows:

§ 405.1004 Right to a review of QIC notice of dismissal.

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ or attorney adjudicator if—

(1) The party files a written request for review within 60 calendar days after receipt of the notice of the QIC's dismissal.

* * * * *

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the QIC's dismissal.

(b) If the ALJ or attorney adjudicator determines that the QIC's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC for a reconsideration in accordance with § 405.1056.

(c) If the ALJ or attorney adjudicator affirms the QIC's dismissal of a reconsideration request, he or she issues a notice of decision affirming the QIC dismissal in accordance with § 405.1046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of a QIC's dismissal in accordance with § 405.1052(b).

■ 24. Section 405.1006 is amended by—

■ a. Revising the section heading and paragraphs (d)(1) introductory text, (d)(1)(ii), and (d)(2).

■ b. Adding paragraphs (d)(3) through (7).

■ c. Revising paragraphs (e)(1) introductory text, (e)(1)(ii) and (iii), (e)(2) introductory text, and (e)(2)(ii) and (iii).

The revisions and additions read as follows:

§ 405.1006 Amount in controversy required for an ALJ hearing and judicial review.

* * * * *

(d) * * *

(1) *In general.* In situations other than those described in paragraphs (d)(3) through (7) of this section, the amount remaining in controversy is computed as the basis for the amount in controversy for the items and services in the disputed claim, as defined in paragraph (d)(2) of this section, reduced by—

* * * * *

(ii) Any deductible and/or coinsurance amounts that may be collected for the items or services.

(2) *Basis for the amount in controversy.* For purposes of calculating the amount in controversy under paragraph (d)(1) of this section, the basis for the amount in controversy is defined as follows:

(i) *General rule.* For situations other than those described in paragraphs (d)(2)(ii) and (iii) of this section, the basis for the amount in controversy is determined as follows:

(A) For items and services with a published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy is the allowable amount, which is the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service.

(B) For items and services with no published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy is the billed charges submitted on the claim for those items or services.

(ii) *Beneficiary financial responsibility.* For items and services for which a beneficiary has been determined to be financially responsible, the basis for the amount in controversy is the actual amount charged to the beneficiary (or the maximum amount the beneficiary may be charged if no bill has been received) for the items and services in the disputed claim.

(iii) *Refunds of amounts previously collected.* If a beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authority, the basis for the amount in controversy is the actual amount originally charged to the beneficiary for those items or services.

(3) *Limitation on liability.* When payment is made for items or services under section 1879 of the Act or § 411.400 of this chapter, or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is calculated in accordance with paragraphs (d)(1) and (d)(2)(i) of this section, except there is no deduction under paragraph (d)(1)(i) for expenses that are paid under § 411.400 of this chapter or as a result of liability that is limited under § 411.402 of this chapter.

(4) *Item or service terminations.* When a matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services, the amount in controversy is calculated in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, except that the basis for the amount in controversy and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services the beneficiary asserts should have been covered based on the beneficiary's current condition, and Medicare payment were not made for the items or services.

(5) *Overpayments.* Notwithstanding paragraphs (d)(1) and (2) of this section, when an appeal involves an identified overpayment, the amount in controversy is the amount of the overpayment specified in the demand letter for the items or services in the disputed claim. When an appeal involves an estimated overpayment amount determined through the use of statistical sampling and extrapolation, the amount in controversy is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter.

(6) *Coinsurance and deductible challenges.* Notwithstanding paragraphs (d)(1) and (2) of this section, for appeals filed by beneficiaries challenging only the computation of a coinsurance amount or the amount of a remaining deductible, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct.

(7) *Fee schedule or contractor price challenges.* Notwithstanding paragraphs (d)(1) and (2) of this section, for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected on the published fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services.

(e) * * *

(1) *Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

* * * * *

(ii) The appellant(s) requests aggregation of claims appealed in the same request for ALJ hearing, or in multiple requests for an ALJ hearing filed with the same request for aggregation, and the request is filed within 60 calendar days after receipt of all of the reconsiderations being appealed; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

* * * * *

(ii) The appellant(s) requests aggregation of the claims for an ALJ hearing in the same request for escalation; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

* * * * *

■ 25. Section 405.1008 is revised to read as follows:

§ 405.1008 Parties to the proceedings on a request for an ALJ hearing.

The party who filed the request for hearing and all other parties to the reconsideration are parties to the proceedings on a request for an ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in § 405.1012.

■ 26. Section 405.1010 is revised to read as follows:

§ 405.1010 When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS or a contractor can participate.* (1) CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in any proceedings before the ALJ, including the hearing.

(b) *How an election is made.* (1) *No notice of hearing.* If CMS or a contractor elects to participate before receipt of a notice of hearing, or when a notice of hearing is not required, it must send written notice of its intent to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request for hearing is not yet assigned to an ALJ or attorney adjudicator, and the parties who were sent a copy of the notice of reconsideration.

(2) *Notice of hearing.* If CMS or a contractor elects to participate after receipt of a notice of hearing, it must send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

(3) *Timing of election.* CMS or a contractor must send its notice of intent to participate—

(i) If no hearing is scheduled, no later than 30 calendar days after notification that a request for hearing was filed; or

(ii) If a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing.

(c) *Roles and responsibilities of CMS or a contractor as a participant.* (1) Subject to paragraphs (d)(1) through (d)(3) of this section, participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

(2) When CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties. However, the parties may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS or contractor position papers and written testimony are subject to the following:

(i) A position paper or written testimony must be submitted by within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing if a hearing is scheduled unless the ALJ grants additional time to submit the position paper or written testimony.

(ii) A copy of any position paper or written testimony it submits to OMHA must be sent to—

(A) The parties who were sent a copy of the notice of reconsideration, if the position paper or written testimony is being submitted before receipt of a notice of hearing for the appeal; or

(B) The parties who were sent a copy of the notice of hearing, if the position paper or written testimony is being submitted after receipt of a notice of hearing for the appeal.

(iii) If CMS or a contractor fails to send a copy of its position paper or written testimony to the parties or fails to submit its position paper or written testimony within the time frames described in this paragraph, the position paper or written testimony will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS or a contractor has been made a party to a hearing in accordance with § 405.1012, no entity that elected to be a participant in the proceedings in accordance with this section (or that elected to be a party to the hearing but was made a participant in accordance with § 405.1012(d)(1)) may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(2) If CMS or a contractor did not elect to be a party to a hearing in accordance with § 405.1012 and more than one entity elected to be a participant in the proceedings in accordance with this section, only the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the oral hearing. Entities that filed a subsequent response to the notice of hearing may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(3) If CMS or a contractor is precluded from participating in the oral hearing under paragraph (d)(1) or (2) of this section, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the election was not timely filed or the election was not sent to the correct parties.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election in accordance with this section.

(i) If no hearing is scheduled or the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a hearing is scheduled, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice must be sent as soon as possible after the oral notice is provided.

■ 27. Section 405.1012 is revised to read as follows:

* * * * *

§ 405.1012 When CMS or its contractors may be a party to a hearing.

(a) *When CMS or a contractor can elect to be a party to a hearing.* (1) Unless the request for hearing is filed by an unrepresented beneficiary, and unless otherwise provided in this section, CMS or one of its contractors may elect to be a party to the hearing upon filing a notice of intent to be a party to the hearing in accordance with paragraph (b) of this section no later than 10 calendar days after the QIC receives the notice of hearing.

(2) An ALJ may request, but may not require, CMS and/or one or more of its contractors to be a party to the hearing. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to be a party to the hearing.

(b) *How an election is made.* If CMS or a contractor elects to be a party to the hearing, it must send written notice to the ALJ and the parties identified in the notice of hearing of its intent to be a party to the hearing.

(c) *Roles and responsibilities of CMS or a contractor as a party.* (1) As a party, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties.

(2) CMS or contractor position papers, written testimony, and evidentiary submissions are subject to the following:

(i) Any position paper, written testimony, and/or evidence must be submitted no later than 5 calendar days prior to the hearing unless the ALJ grants additional time to submit the position paper, written testimony, and/or evidence.

(ii) A copy of any position paper, written testimony, and/or evidence it submits to OMHA must be sent to the parties who were sent a copy of the notice of hearing.

(iii) If CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit its position paper, written testimony, and/or evidence within the time frames described in this section, the position paper, written testimony, and/or evidence will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS and one or more contractors, or multiple contractors, file an election to be a party to the hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under § 405.1010, subject to § 405.1010(d)(1) and (3), unless the ALJ grants leave to an entity to also be a party to the hearing in accordance with paragraph (d)(2) of this section.

(2) If CMS or a contractor filed an election to be a party in accordance with this section but is precluded from being made a party under paragraph (d)(1) of this section, the ALJ may grant leave to be a party to the hearing if the ALJ determines that the entity's participation as a party is necessary for a full examination of the matters at issue.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who were sent the notice of hearing.

(i) If the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the decision, dismissal, or remand notice is mailed.

(ii) If the election was submitted before the hearing occurs, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing must be sent as soon as possible after the oral notice is provided.

■ 28. Section 405.1014 is revised to read as follows:

§ 405.1014 Request for an ALJ hearing or a review of a QIC dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of a QIC dismissal must be made in writing. The request must include all of the following—

(i) The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed, and the beneficiary's telephone number if the beneficiary is the appealing party and not represented.

(ii) The name, address, and telephone number, of the appellant, when the appellant is not the beneficiary.

(iii) The name, address, and telephone number, of the designated representative, if any.

(iv) The Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed.

(v) The dates of service of the claim(s) being appealed, if applicable.

(vi) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(vii) A statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by the HHS Office of Inspector General or other law enforcement agencies.

(viii) For requests filed by providers, suppliers, Medicaid State agencies, applicable plans, or a beneficiary who is represented by a provider, supplier or Medicaid State agency, the amount in controversy applicable to the disputed claim determined in accordance with § 405.1006, unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services.

(2) The appellant must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) Special rule for appealing statistical sample and/or extrapolation. If the appellant disagrees with how a statistical sample and/or extrapolation was conducted, the appellant must—

(i) Include the information in paragraphs (a)(1) and (2) of this section for each sample claim that the appellant wishes to appeal;

(ii) File the request for hearing for all sampled claims that the appellant wishes to appeal within 60 calendar days of the date the party receives the last reconsideration for the sample claims, if they were not all addressed in a single reconsideration; and

(iii) Assert the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted in the request for hearing.

(b) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the appellant will be provided with an opportunity to complete the request, and if an adjudication time frame applies, it does not begin until the request is complete. If the appellant fails to provide the information necessary to complete the request within the time frame provided, the appellant's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(c) *When and where to file.* The request for an ALJ hearing or request for review of a QIC dismissal must be filed—

(1) Within 60 calendar days from the date the party receives notice of the QIC's reconsideration or dismissal, except as provided in paragraph (a)(3)(ii) of this section for appeals of extrapolations;

(2) With the office specified in the QIC's reconsideration or dismissal. If the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, any applicable time frame specified in § 405.1016 for deciding the appeal begins on the date the office specified in the QIC's reconsideration or dismissal receives the request for hearing. If the request for hearing is filed with an office, other than the entity office specified in the QIC's reconsideration or dismissal, OMHA must notify the appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame.

(d) *Copy requirement.* (1) The appellant must send a copy of the request for hearing or request for review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. If additional materials submitted with the request are necessary to provide the information required for a complete request in accordance with paragraph (b) of this section, copies of the materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). If additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence, or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence).

(2) Evidence that a copy of the request for hearing or request for review of a QIC dismissal, or a copy of submitted evidence or a summary thereof, was sent in accordance with paragraph (d)(1) of this section includes—

(i) Certification on the standard form for requesting an ALJ hearing or requesting a review of a QIC dismissal that a copy of the request is being sent to the other parties;

(ii) An indication, such as a copy or "cc" line, on a request for hearing or request for review of a QIC dismissal that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipient;

(iii) An affidavit or certificate of service that identifies the name and address of the recipient, and what was sent to the recipient; or

(iv) A mailing or shipping receipt that identifies the name and address of the recipient, and what was sent to the recipient.

(3) If the appellant fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of submitted evidence or a summary thereof, as described in paragraph (d)(1) of this section, the appellant will be provided with an additional opportunity to send the request, materials, and/or evidence or summary thereof, and if an adjudication time frame applies, it begins upon receipt of evidence that the request, materials, and/or evidence or summary thereof were sent. If the appellant again fails to provide evidence that the request, materials, and/or evidence or summary thereof were sent within the additional time frame provided to send the request, materials, and/or evidence or summary thereof, the appellant's request for hearing or request for review of a QIC dismissal will be dismissed.

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review of a QIC dismissal is not filed within 60 calendar days of receipt of the QIC's reconsideration or dismissal, an appellant may request an extension for good cause (See § 405.942(b)(2) and (3)).

(2) Any request for an extension of time must be in writing, give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or request for review of a QIC dismissal with the office specified in the notice of reconsideration or dismissal.

(3) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of a QIC dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of a QIC dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or attorney adjudicator uses the standards set forth in § 405.942(b)(2) and (3).

(4) If a request for hearing is not timely filed, any applicable adjudication period in § 405.1016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(5) A determination granting a request to extend the filing deadline is not subject to further review.

■ 29. Section 405.1016 is revised to read as follows:

§ 405.1016 Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration.

(a) *Adjudication period for appeals of QIC reconsiderations.* When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *When the adjudication period begins.* (1) Unless otherwise specified in this subpart, the adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the office specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(2) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c) of this section, the remanded appeal will

be subject to the adjudication time frame of paragraph (a) of this section beginning on the date that OMHA receives the Council remand.

(c) *Adjudication period for escalated requests for QIC reconsiderations.* When an appeal is escalated to OMHA because the QIC has not issued a reconsideration determination within the period specified in § 405.970, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180 calendar day period beginning on the date that the request for escalation is received by OMHA in accordance with § 405.970, unless the 180 calendar day period is extended as provided in this subpart.

(d) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the appellant may waive the adjudication period specified in paragraphs (a) and (c) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the appellant.

(2) The adjudication periods specified in paragraphs (a) and (c) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction; or

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an appellant, provided no other party also filed a request for hearing on the same claim at issue.

(e) *Effect of exceeding adjudication period.* If an ALJ or attorney adjudicator fails to issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in this section, subject to paragraphs (b) and (d) of this section, the party that filed the request for hearing may escalate the appeal in accordance with paragraph (f) of this section. If the party that filed the request for hearing does not elect to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand.

(f) *Requesting escalation.* (1) *When and how to request escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending with OMHA at the end of the applicable adjudication period under paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, may exercise the option of escalating the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council and sending a copy of the request to escalate to the other parties who were sent a copy of the QIC reconsideration.

(2) *Escalation.* If the request for escalation meets the requirements of paragraph (f)(1) of this section and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation, or 5 calendar days from the end of the applicable adjudication period set forth in paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, OMHA will take the following actions—

(i) Send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of this section, the QIC reconsideration will be the decision that is subject to Council review consistent with § 405.1102(a), and the appeal will be escalated to the Council for a review in accordance with § 405.1108; and

(ii) Forward the case file to the Council.

(3) *Invalid escalation request.* If an ALJ or attorney adjudicator determines the request for escalation does not meet the requirements of paragraph (f)(1) of this section, OMHA will send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation.

■ 30. Section 405.1018 is revised to read as follows:

§ 405.1018 Submitting evidence.

(a) *When evidence may be submitted.* Except as provided in this section, parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with § 405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(b) *Effect on adjudication period.* If a party submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 405.1016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(c) *New evidence.* (1) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see § 405.1028).

(2) If a statement explaining why the evidence was not previously submitted to the QIC or a prior decision-maker is not included with the evidence, the evidence will not be considered.

(d) *When this section does not apply.* The requirements of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary.

■ 31. Section 405.1020 is amended by—
■ a. Revising paragraphs (b), (c), (d), and (e)(3) and (4).
■ b. Adding paragraphs (g)(3)(vii) and (viii).
■ c. Revising paragraphs (h), (i) paragraph heading, and (i)(1), (2), (4), and (5).
■ d. Adding paragraph (j).

The revisions and additions read as follows:

§ 405.1020 Time and place for a hearing before an ALJ.

* * * * *

(b) *Determining how appearances are made.* (1) *Appearances by unrepresented beneficiaries.* The ALJ will direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by video-teleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ find good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented beneficiary.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) VTC or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by individuals other than unrepresented beneficiaries.* The ALJ will direct that the appearance of an individual, other than an unrepresented beneficiary who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, also may find good cause that an in-person hearing should be conducted if—

(A) VTC and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to all parties that filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination or may be found liable based on a review of the record, the QIC that issued the reconsideration, and CMS or a contractor that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the party or representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing.

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 405.1038(b). As provided in § 405.1000, an ALJ may require the parties to attend a hearing if it is necessary to decide the case. If an ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) * * *

(3) The request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral requests for a rescheduled hearing in writing and maintain the documentation in the administrative record.

(4) The ALJ may change the time or place of the hearing if the party has good cause.

* * * * *

(g) * * *

(3) * * *

(vii) The party or representative has a prior commitment that cannot be changed without significant expense.

(viii) The party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the appellant for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 405.1016.

(i) *A party's request for an in-person or VTC hearing.* (1) If an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or an in-person hearing.

(2) The party must state the reason for the objection and state the time and/or place he or she wants an in-person or VTC hearing to be held.

* * * * *

(4) When a party's request for an in-person or VTC hearing as specified under paragraph (i)(1) of this section is granted and an adjudication time frame applies in accordance with § 405.1016, the ALJ issues a decision, dismissal, or remand to the QIC within the adjudication time frame specified in § 405.1016 (including any applicable extensions provided in this subpart) unless the party requesting the hearing agrees to waive such adjudication time frame in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person or by VTC before the ALJ.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing in accordance with § 405.1022(a).

■ 32. Section 405.1022 is revised to read as follows:

§ 405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the parties and other potential participants, as provided in § 405.1020(c) at their last known address, or given by personal service, except to a party or potential participant who indicates in writing that it does not wish to receive this notice. The notice is mailed, transmitted, or served at least 20 calendar days before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 405.1032.

(2) The notice will inform the parties that they may designate a person to represent them during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the appellant fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(5) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at § 405.1020(i) for notifying the ALJ of

their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the party for an explanation.

(2) If the party states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the party and in accordance with OMHA procedures.

(3) The party may request that the ALJ reschedule the hearing in accordance with § 405.1020(e).

■ 33. Section 405.1024 is amended by revising paragraphs (b) and (c) to read as follows:

§ 405.1024 Objections to the issues.

* * * * *

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing.

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

■ 34. Section 405.1026 is revised to read as follows:

§ 405.1026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator cannot adjudicate an appeal if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator considers the party's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the party may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 405.1100 through § 405.1130. The Council will then consider whether the decision or dismissal should be revised or if applicable, a new hearing held before another ALJ. If the case is escalated to the Council after a hearing is held but before the ALJ issues a decision, the Council considers the reasons the party objected to the ALJ during its review of the case and, if the Council deems it necessary, may remand the case to another ALJ for a hearing and decision.

(d) If the party objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication time frame that applies to the appeal in accordance with § 405.1016 is extended by 14 calendar days.

■ 35. Section 405.1028 is revised to read as follows:

§ 405.1028 Review of evidence submitted by parties.

(a) *New evidence*—(1) *Examination of any new evidence.* After a hearing is requested but before a hearing is held by an ALJ or a decision is issued if no hearing is held, the ALJ or attorney adjudicator will examine any new evidence submitted in accordance with § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the OMHA level.

(2) *Determining if good cause exists.* An ALJ or attorney adjudicator finds good cause when—

(i) The new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration;

(ii) The new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with § 405.1032(b)(1);

(iii) The party was unable to obtain the evidence before the QIC issued its reconsideration and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration;

(iv) The party asserts that the evidence was submitted to the QIC or another contractor and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration; or

(v) In circumstances not addressed in paragraphs (a)(2)(i) through (iv) of this section, the ALJ or attorney adjudicator determines that the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration.

(3) *If good cause does not exist.* If the ALJ or attorney adjudicator determines that there was not good cause for submitting the evidence for the first time at the OMHA level, the ALJ or attorney adjudicator must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(4) *Notification to parties.* If a hearing is conducted, as soon as possible, but no later than the start of the hearing, the ALJ must notify all parties and participants who responded to the notice of hearing whether the evidence will be considered or is excluded from consideration.

(b) *Duplicative evidence.* The ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA.

■ 36. Section 405.1030 is revised to read as follows:

§ 405.1030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) At the hearing, the ALJ fully examines the issues, questions the parties and other witnesses, and may accept evidence that is material to the issues consistent with §§ 405.1018 and 405.1028.

(2) The ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, or that address an issue before the ALJ for which the ALJ determines he or she has sufficient information or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter, in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that a party or party's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing, the ALJ may excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with an opportunity to offer testimony and/or argument. If a party or representative was excused from the hearing, the ALJ will provide the party or representative with an opportunity to submit written statements and affidavits

in lieu of testimony and/or argument at the hearing, and the party or representative may request a recording of the hearing in accordance with § 405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause in accordance with § 405.1028 for not producing the evidence earlier.

(d) *Effect of New evidence on adjudication period.* If an appellant, other than an unrepresented beneficiary, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in § 405.1016 is extended in accordance with § 405.1018(b).

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with § 405.1022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the continuance and an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 405.1022, except that the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

■ 37. Section 405.1032 is revised to read as follows:

§ 405.1032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term "party" does not include a representative of CMS or one of its contractors that may be participating in the hearing.)

(b) *New issues*—(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS or its contractor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS or its contractor for the first time to the ALJ. The ALJ or any party may raise a new issue relating to a claim or appealed matter specified in the request for hearing; however, the ALJ may only consider a new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the parties that were or will be sent the notice of hearing about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the parties will have at least 10 calendar days after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding claims to a pending appeal.* (1) Claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims in accordance with § 405.1014(e).

(2) Before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates the information that constitutes a complete request for hearing in accordance with § 405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with § 405.1014(d).

(d) *Appeals involving statistical sampling and extrapolations.* (1) *Generally.* If the appellant does not assert the reasons the appellant disagrees with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), issues related to how the statistical sample and extrapolation were conducted shall not be considered or decided.

(2) *Consideration of sample claims.* If a party asserts a disagreement with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), paragraphs (a) through (c) of this section apply to the adjudication of the sample claims but, in deciding issues related to how a statistical sample and/or extrapolation was conducted the ALJ or attorney adjudicator must base his or her decision on a review of the entire sample to the extent appropriate to decide the issue.

■ 38. Section 405.1034 is revised to read as follows:

§ 405.1034 Requesting information from the QIC.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors.

(2) "Can be provided only by CMS or its contractors" means the information

is not publicly available, is not in the possession of, and cannot be requested and obtained by one of the parties. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS or contractor Web site or information in an official CMS or DHHS publication (including, but not limited to, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions).

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The QIC has 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or another contractor.

(d) If an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever occurs first.

§ 405.1036 [Amended]

■ 39. Section 405.1036 is amended by—

■ a. Amending paragraph (b)(1) by removing the phrase "send the ALJ" and adding "submit to OMHA" in its place.

■ b. Removing paragraph (d).

■ c. Redesignating paragraph (g) as new paragraph (d).

■ d. Amending paragraphs (f)(5)(i), (ii), (iii), (iv), (v), and (vi) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ e. Amending paragraphs (f)(5)(i) and (ii) by removing the term "MAC's" and adding "Council's" in its place.

■ f. Amending paragraph (f)(5)(i) by removing the phrase "specified in § 405.1102, § 405.1104, or § 405.1110" and adding "specified in § 405.1016(e) and (f), § 405.1102, or § 405.1110" in its place.

■ g. Amending paragraph (f)(5)(ii) by removing the phrase "discovery ruling" each time it appears and adding "subpoena ruling" in its place.

■ 40. Section 405.1037 is amended by—

■ a. Revising paragraph (a)(1).

■ b. Amending paragraph (e)(1) by removing the phrase "specified in § 405.1100, § 405.1102, § 405.1104, or § 405.1110" and adding "specified in § 405.1016(e) and (f), § 405.1100, § 405.1102, or § 405.1110" in its place.

■ c. Amending paragraphs (e)(1), (e)(2) introductory text, (e)(2)(i), (ii), (iii), (iv), and (v) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ d. Amending paragraphs (e)(1) and (e)(2)(i) by removing the term "MAC's" and adding "Council's" in its place.

■ e. Revising paragraph (f).

The revisions read as follows:

§ 405.1037 Discovery.

(a) * * *

(1) Discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with § 405.1012.

* * * * *

(f) *Adjudication period.* If an adjudication period applies to the appeal in accordance with § 405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery.

■ 41. Section 405.1038 is revised to read as follows:

§ 405.1038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear.* (1) An ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) All the parties who would be sent a notice of hearing in accordance with § 405.1020(c) indicate in writing that they do not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ, and there are no other parties who would be sent a notice of hearing in accordance with § 405.1020(c) and who wish to appear.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

■ 42. Section 405.1040 is revised to read as follows:

§ 405.1040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties who will be or were sent a notice of hearing in accordance with § 405.1020(c), and CMS or a contractor that has elected to be a participant in the proceedings or party to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice if the parties consent to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(d) The ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. If a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties.

■ 43. Section 405.1042 is revised to read as follows:

§ 405.1042 The administrative record.

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations,

and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

(3) A party may request and review a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed or the case is escalated to the Council, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if a party seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, a party may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. The party may be asked to pay the costs of providing these items.

(2) If a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response.

(3) If a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the requesting party obtains consent from the individual.

■ 44. Section 405.1044 is revised to read as follows:

§ 405.1044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the appeals are consolidated for hearing. In considering the appellant's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an appellant to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an appellant to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§ 405.1020 and 405.1022.

(b) *Consolidated or separate decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the appellant or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement in accordance with § 405.1006 and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants.

■ 45. Section 405.1046 is revised to read as follows:

§ 405.1046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions. OMHA mails or otherwise transmits a copy of the decision to all the parties at their last known address and the QIC that issued the reconsideration or from which the appeal was escalated. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ or attorney adjudicator may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with the ALJ's or attorney adjudicator's decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to § 405.1028, a discussion of the new evidence and the good cause determination that was made.

(iii) The procedures for obtaining additional information concerning the decision; and

(iv) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the

ALJ or attorney adjudicator, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the contractor for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's or attorney adjudicator's decision is a new initial determination under § 405.924.

(b) *Decisions on requests for review of a QIC dismissal*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of a QIC dismissal, or the QIC's dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the QIC's dismissal. OMHA mails or otherwise transmits a copy of the decision to all the parties that received a copy of the QIC's dismissal.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to all the parties at their last known address.

■ 46. Section 405.1048 is revised to read as follows:

§ 405.1048 The effect of an ALJ's or attorney adjudicator's decision.

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding on all parties unless—

(1) A party requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 405.1110, and the Council issues a final decision or remand order or the appeal is escalated to Federal district court under the provisions at § 405.1132 and the Federal district court issues a decision.

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 405.980;

(3) The expedited access to judicial review process at § 405.990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 405.1138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures in § 405.980.

§ 405.1050 [Amended]

■ 47. Section 405.1050 is amended by—

■ a. Amending the section heading by removing the phrase "an ALJ" and adding "OMHA" in its place.

■ b. Amending the text of the section by removing the phrase "pending before an ALJ" and adding "pending before OMHA" in its place, and by removing the term "the ALJ" and adding "OMHA" in its place.

■ c. Amending the section heading and the text of the section by removing the term "MAC" each time it appears and adding "Council" in its place.

■ 48. Section 405.1052 is revised to read as follows:

§ 405.1052 Dismissal of a request for a hearing before an ALJ or request for review of a QIC dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar days after the hearing, or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the party acknowledged the notice of hearing, the ALJ sends a notice to the party at the last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language), that the party may have.

(2) The person or entity requesting a hearing has no right to it under § 405.1002.

(3) The party did not request a hearing within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 405.1014(e).

(4) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to § 405.1014.

(5) The ALJ or attorney adjudicator dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The appellant abandons the request for hearing. An ALJ or attorney adjudicator may conclude that an appellant has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(7) The appellant's request is not complete in accordance with

§ 405.1014(a)(1) or the appellant did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(b) *Dismissal of request for review of a QIC dismissal.* An ALJ or attorney adjudicator dismisses a request for review of a QIC dismissal under any of the following conditions:

(1) The person or entity requesting a review of a dismissal has no right to it under § 405.1004.

(2) The party did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 405.1014(e).

(3) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(i) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1004.

(iii) No other individual or entity filed a valid and timely request for a review of the QIC dismissal in accordance to § 405.1014.

(4) The appellant's request is not complete in accordance with § 405.1014(a)(1) or the appellant did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if only one party requested the hearing or review of the QIC dismissal and that party asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of a QIC dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing or review of the QIC dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to all parties who were sent a copy of the request for hearing or review at their last known address. The notice states that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action. The appeal will proceed with respect to any other parties who filed a valid request for hearing or review regarding the same claim or disputed matter.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 6 months of the date of the notice of dismissal.

■ 49. Section 405.1054 is revised to read as follows:

§ 405.1054 Effect of dismissal of a request for a hearing or request for review of QIC dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 405.1108(b), or vacated by the ALJ or attorney adjudicator under § 405.1052(e).

(b) The dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e).

■ 50. Section 405.1056 is added before the undesignated center heading "Applicability of Medicare Coverage Policies" to read as follows:

§ 405.1056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with § 405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in § 405.1034, the ALJ or attorney adjudicator may issue a remand directing the QIC or other contractor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the QIC does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the QIC to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the QIC or another contractor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with § 405.1016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the QIC issued a reconsideration that addressed coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required under this subpart) or the request for redetermination was dismissed, the reconsideration will be remanded to the QIC, or its successor to re-adjudicate the request for reconsideration.

(c) *Requested remand*—(1) *Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors may jointly request a remand of the appeal to the entity that conducted the reconsideration. The request must include the reasons why the appeal should be remanded and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding a QIC's dismissal of a request for reconsideration.* Consistent with § 405.1004(b), an ALJ or attorney adjudicator will remand a case to the appropriate QIC if the ALJ or attorney adjudicator determines that a QIC's dismissal of a request for reconsideration was in error.

(e) *Relationship to local and national coverage determination appeals process.* (1) An ALJ or attorney adjudicator remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to §§ 426.460(b)(1), 426.488(b), or 426.560(b)(1) of this chapter.

(2) Unless the appellant is entitled to relief pursuant to §§ 426.460(b)(1), 426.488(b), or 426.560(b)(1) of this chapter, the ALJ or attorney adjudicator applies the LCD or NCD in place on the date the item or service was provided.

(f) *Notice of a remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant in the proceedings or party to the hearing. The notice states that there is a right to request that the Chief ALJ or a designee review the remand.

(g) *Review of remand.* Upon a request by a party or CMS or one of its contractors filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review.

■ 51. Section 405.1058 is added before the undesignated center heading "Applicability of Medicare Coverage Policies" to read as follows:

§ 405.1058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with § 405.1056(g).

§ 405.1060 [Amended]

■ 52. Section 405.1060 is amended by—

■ a. Amending paragraph (a)(4) by removing the term "ALJs" and adding "ALJs and attorney adjudicators" in its place.

■ b. Amending paragraphs (a)(4), (c) paragraph heading, (c)(1), and (c)(2) by removing the term "MAC" and adding "Council" in its place.

■ c. Amending paragraphs (b) paragraph heading, (b)(1), and (b)(2) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

§ 405.1062 [Amended]

■ 53. Section 405.1062 is amended by—

■ a. Amending the section heading and paragraphs (a) and (b) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending the section heading and paragraph (b) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.

■ c. Amending paragraph (a) by removing the term "ALJs" and adding "ALJs and attorney adjudicators" in its place.

■ d. Amending paragraph (c) by removing the phrase "An ALJ or MAC" and adding "An ALJ or attorney adjudicator or the Council" in its place.

■ 54. Section 405.1063 is revised to read as follows:

§ 405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

§ 405.1064 [Removed]

■ 55. Section 405.1064 is removed.

■ 56. Section 405.1100 is revised to read as follows:

§ 405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal.

(b) Under circumstances set forth in §§ 405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case.

(c) When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review. The Council issues a final decision or dismissal order or remands a case to the ALJ or attorney adjudicator within 90 calendar days of receipt of the appellant's request for review, unless the 90 calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the OMHA level to the Council, the Council will issue a final decision or dismissal order or remand the case to the OMHA Chief ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

■ 57. Section 405.1102 is revised to read as follows:

§ 405.1102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) A party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a Council review if the party files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

(2) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) A party requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the Council; and

(3) It explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at § 405.942(b)(2) and (3).

(c) A party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC, affirmation of a QIC's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC dismissal.

(d) For purposes of requesting Council review (§§ 405.1100 through 405.1140), unless specifically excepted, the term "party", includes CMS where CMS has entered into a case as a party according to § 405.1012. The term, "appellant," does not include CMS, where CMS has entered into a case as a party according to § 405.1012.

§ 405.1104 [Removed]

■ 58. Section 405.1104 is removed.

■ 59. Section 405.1106 is revised to read as follows:

§ 405.1106 Where a request for review or escalation may be filed.

(a) When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The appellant must also send a copy of the request for review to the other parties to the ALJ or attorney adjudicator decision or dismissal who received notice of the decision or dismissal. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties to the ALJ or attorney adjudicator decision or dismissal receive notice of the request for Council review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council 's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under § 405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation. In a case that has been escalated from OMHA, the Council's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the Council.

§ 405.1108 [Amended]

■ 60. Section 405.1108 is amended by—

■ a. Amending the section heading and paragraphs (a), (b), (c), (d) introductory text, (d)(2), and (4) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending paragraphs (a), (b), (c), (d)(1), and (5) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.

■ c. Amending paragraphs (a) and (b) by removing the term "ALJ's" each time it appears and adding "ALJ's or attorney adjudicator's" in its place.

■ d. Amending paragraph (b) by removing the first use of "dismissal" in the paragraph and adding "dismissal of a request for a hearing" in its place.

■ e. Amending paragraph (d) introductory text by removing the term "ALJ level" and adding "OMHA level" in its place.

■ f. Amending paragraph (d)(3) by removing the phrase "to an ALJ" and adding "to OMHA" in its place.

■ 61. Section 405.1110 is revised to read as follows:

§ 405.1110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or any of its contractors may refer a case to the Council for it to consider reviewing under this authority anytime within 60 calendar days after the date of an ALJ's or attorney adjudicator's decision or dismissal.

(b) *Referral of cases.* (1) CMS or any of its contractors may refer a case to the Council if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the Council take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the OMHA level; and

(ii) In CMS' view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's decision or dismissal is issued. The written referral will state the reasons why CMS believes the Council must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's or attorney adjudicator's action who received a copy of the hearing decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d), and to the OMHA Chief ALJ. Parties to the ALJ's or attorney adjudicator's action may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice. A party submitting comments to the Council must send such comments to CMS and all other parties to the ALJ's or attorney adjudicator's action who received a copy of the hearing decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d).

(c) *Standard of review*—(1) *Referral by CMS after participation at the OMHA level.* If CMS or its contractor participated in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the OMHA proceedings or appear as a party.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(d) *Council's action.* If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings or may dismiss a hearing request. The Council must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The Council may not, however, issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the Council does not act within the applicable adjudication deadline, the ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the ALJ's or attorney adjudicator's action.

■ 62. Section 405.1112 is revised to read as follows:

§ 405.1112 Content of request for review.

(a) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare health insurance claim number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's or attorney adjudicator's decision or dismissal order, if any; and the name and signature of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ's or attorney adjudicator's action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's or attorney adjudicator's decision, dismissal, or other determination being appealed. For example, if the party requesting review believes that the ALJ's or attorney adjudicator's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

§ 405.1114 [Amended]

■ 63. Section 405.1114 is amended by—

■ a. Amending the introductory text and paragraphs (b) and (c)(1) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending paragraph (c)(3) by removing the phrase "ALJ hearing" and adding "ALJ's or attorney adjudicator's action" in its place.

§ 405.1116 [Amended]

■ 64. Section 405.1116 is amended by—

■ a. Removing the term "MAC" each time it appears in the heading and text and adding "Council" in its place.

■ b. Removing the term "MAC's" and adding "Council's" in its place.

■ c. Removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

§ 405.1118 [Amended]

■ 65. Section 405.1118 is amended by—
■ a. Removing the term "MAC" each time it appears in the heading and text and adding "Council" in its place.
■ b. Removing the phrase "ALJ hearing" and adding "ALJ's or attorney adjudicator's action" in its place.
■ c. Removing the phrase "the exhibits list" and adding "any index of the administrative record" in its place.
■ d. Removing the term "tape" and adding "audio recording" in its place.
■ e. Removing the term "MAC's" and adding "Council's" in its place.

§ 405.1120 [Amended]

■ 66. Section 405.1120 is amended in the heading and text by removing the term "MAC" each time it appears and adding "Council" in its place.

§ 405.1122 [Amended]

■ 67. Section 405.1122 is amended by—
■ a. Amending the section heading and paragraphs (a) paragraph heading, (a)(1) and (2), (b) paragraph heading, (b)(1) and (2), (c)(1), (2), and (3) introductory text, (c)(3)(ii), (d)(1) and (3), (e)(1), (2), (3), and (4), and (f)(1), (2), and (3) by removing the term "MAC" each time it appears and adding "Council" in its place.
■ b. Amending paragraphs (e)(5) and (6), and (f)(2) by removing the term "MAC's" and adding "Council's" in its place.
■ c. Amending paragraph (a)(1) by removing the term "hearing decision" and adding "ALJ's or attorney adjudicator's decision" in its place.
■ d. Amending paragraphs (a)(1) and (b)(1) by removing the term "ALJ level" and adding "OMHA level" in its place.
■ e. Amending paragraphs (a)(1) and (2), (b)(1) and (2), (c)(2), (c)(3) introductory text, and (c)(3)(i) and (ii) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.
■ f. Amending paragraphs (a) paragraph heading and (a)(1) by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.
■ g. Amending paragraph (a)(2) by removing the term "hearing record" and adding "administrative record" in its place.

§ 405.1124 [Amended]

■ 68. Section 405.1124 is amended by removing the term "MAC" each time it appears and adding "Council" in its place.

§ 405.1126 [Amended]

■ 69. Section 405.1126 is amended by—
■ a. Amending the section heading and paragraphs (a), (b), (c), (d) paragraph heading, (d)(1) and (2), (e) paragraph heading, and (e)(1) and (2) by removing the term "MAC" each time it appears and adding "Council" in its place.
■ b. Amending paragraph (b) by removing the term "MAC's" and adding "Council's" in its place.
■ c. Amending paragraphs (a), (b), (c), (d) paragraph heading, and (e)(2) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.
■ d. Amending paragraph (e)(2) by adding "if applicable" after the word "rehearing".

§ 405.1128 [Amended]

■ 70. Section 405.1128 is amended by—
■ a. Amending the section heading and paragraphs (a), (b), and (c) by removing the term "MAC" each time it appears and adding "Council" in its place.
■ b. Amending paragraph (a) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.
■ c. Amending paragraph (b) by removing the term "ALJ hearing decision" and adding "ALJ's or attorney adjudicator's decision" in its place.

§ 405.1130 [Amended]

■ 71. Section 405.1130 is amended in the section heading and text by removing the term "MAC's" each time it appears and adding "Council's" in its place.

§ 405.1132 [Amended]

■ 72. Section 405.1132 is amended by—
■ a. Amending paragraphs (a) introductory text, (a)(2), and (b) by removing the term "MAC" each time it appears and adding "Council" in its place.
■ b. Amending paragraph (b) by removing the term "MAC's" and adding "Council's" in its place.
■ c. Amending paragraphs (a) introductory text, (a)(1), and (b) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.

§ 405.1134 [Amended]

■ 73. Section 405.1134 is amended by—
■ a. Amending paragraph (a) by removing the term "MAC's" and adding "Council's" in its place.
■ b. Amending paragraphs (b)(3) and (c) by removing the term "MAC" and adding "Council" in its place.

§ 405.1136 [Amended]

■ 74. Section 405.1136 is amended by—
■ a. Amending paragraphs (a)(1) and (2), and (c)(3) by removing the term "MAC" each time it appears and adding "Council" in its place.
■ b. Amending paragraph (a)(1) by removing the term "ALJ's" and adding

"ALJ's or attorney adjudicator's" in its place.

■ c. Amending paragraphs (a)(2) and (c)(2) by removing the term "MAC's" each time it appears and adding "Council's" in its place.

■ d. Amending paragraph (c)(3) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

§ 405.1138 [Amended]

■ 75. Section 405.1138 is amended by—

■ a. Removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

§ 405.1140 [Amended]

■ 76. Section 405.1140 is amended by—

■ a. Amending the section heading and paragraphs (a)(1), (2), and (3), (b)(1), (2), and (3), (c) paragraph heading, (c)(1), (3), and (4), and (d) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending the section heading and paragraphs (a)(1), (2), and (3), (b) paragraph heading, (b)(1), (2), and (3), (c)(1) and (4), and (d) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.

■ c. Amending paragraph (d) by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

■ 77. Section 405.1204 is amended by revising paragraphs (c)(4)(iii) and (c)(5) to read as follows:

§ 405.1204 Expedited reconsiderations.

* * * * *

(c) * * *

(4) * * *

(iii) Information about the beneficiary's right to appeal the QIC's reconsideration decision to OMHA for an ALJ hearing in accordance with subpart I of this part, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to OMHA for an ALJ hearing in accordance with subpart I of this part, if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under § 405.1006.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 78. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 422.561 [Amended]

■ 79. Section 422.561 is amended, in the definition of "Appeal," by removing the phrase "Medicare Appeals Council (MAC)" and adding "Medicare Appeals Council (Council)" in its place.

■ 80. Section 422.562 is amended by—

■ a. Amending paragraph (b)(4)(v) by removing the term "MAC" and adding "Council" in its place.

■ b. Revising paragraphs (c)(1) and (d) to read as follows:

§ 422.562 General provisions.

* * * * *

(c) * * *

(1) If an enrollee receives immediate QIO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care the enrollee is not entitled to review of that issue by the MA organization.

* * * * *

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply under this subpart to the extent they are appropriate, unless the part 405 regulation implements a provision of section 1869 of the Act that is not also in section 1852(g)(5) of the Act.

■ 81. Section 422.594 is amended by revising paragraph (b)(2) to read as follows:

§ 422.594 Notice of reconsidered determination by the independent entity.

* * * * *

(b) * * *

(2) If the reconsidered determination is adverse (that is, does not completely reverse the MA organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of § 422.600;

* * * * *

■ 82. Section 422.602 is amended by revising paragraph (b) to read as follows:

§ 422.602 Request for an ALJ hearing.

* * * * *

(b) *When to file a request.* (1) Except when an ALJ or attorney adjudicator extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 calendar days of receipt of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020.

(2) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary.

* * * * *

■ 83. Section 422.608 is revised to read as follows:

§ 422.608 Medicare Appeals Council (Council) review.

Any party to the ALJ's or attorney adjudicator's decision or dismissal, including the MA organization, who is dissatisfied with the decision or dismissal, may request that the Council review the decision or dismissal. The regulations under part 405 of this chapter regarding Council review apply to matters addressed by this subpart to the extent that they are appropriate, unless the part 405 regulation implements a provision of section 1869 of the Act that is not also in section 1852(g)(5) of the Act.

§ 422.612 [Amended]

■ 84. Section 422.612 is amended by—

■ a. Amending paragraph (a) paragraph heading and introductory text by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

■ b. Amending paragraph (a)(1) by removing the term "Board" and adding "Council" in its place.

■ c. Amending paragraph (b) by removing the term "MAC" each time it appears and adding "Council" in its place.

§ 422.616 [Amended]

■ 85. Section 422.616 is amended in paragraph (a) by removing the terms "ALJ" and "MAC" and adding in their place "ALJ or attorney adjudicator" and "Council" respectively.

§ 422.618 [Amended]

■ 86. Section 422.618 is amended by—

■ a. Amending paragraph (c)(1) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ b. Amending paragraph (c)(2) by removing the terms "Medicare Appeals Council", "Medicare Appeals Council (the Board)", and "Board" and adding "Council" in their place.

§ 422.619 [Amended]

■ 87. Section 422.619 is amended by—

■ a. Amending paragraph (c)(1) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ b. Amending paragraph (c)(2) by removing the terms "Medicare Appeals Council", "Medicare Appeals Council (the Board)", and "Board" and adding "Council" in their place.

§ 422.622 [Amended]

■ 88. Section 422.622 (g)(2) is amended by removing the phrase "may appeal to an ALJ, the MAC, or a federal court" and adding "may appeal to OMHA for an ALJ hearing, the Council, or a federal court" in its place.

§ 422.626 [Amended]

■ 89. Section 422.626(g)(3) is amended by removing the phrase "to an ALJ, the MAC, or a Federal court" and adding "to OMHA for an ALJ hearing, the Council, or a Federal court" in its place.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 90. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

§ 423.560 [Amended]

■ 91. Section 423.560 is amended by amending the definition of "Appeal" by removing the term "Medicare Appeals Council (MAC)" and adding "Medicare Appeals Council (Council) in its place.

■ 92. Section 423.562 is amended by revising paragraphs (b)(4)(v) and (vi) to read as follows:

§ 423.562 General provisions.

* * * * *

(b) * * *

(4) * * *

(v) If the ALJ or attorney adjudicator affirms the IRE's adverse coverage determination, in whole or in part, the right to request Council review of the ALJ's or attorney adjudicator's decision, as specified in § 423.1974.

(vi) If the Council affirms the ALJ's or attorney adjudicator's adverse coverage determination, in whole or in part, the right to judicial review of the decision if the amount in controversy meets the requirements in § 423.1976.

* * * * *

Subpart U—Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, MAC Review, and Judicial Review

■ 93. The heading of subpart U is revised to read as set forth above.

■ 94. Section 423.1968 is revised to read as follows:

§ 423.1968 Scope.

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs and attorney adjudicators, and the Council with respect to reopenings.

(b) ALJs with respect to hearings and decisions or decisions of attorney adjudicators if no hearing is conducted.

(c) The Council with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings and ALJ or attorney adjudicator reviews, Council reviews, and judicial review by a Federal District Court.

■ 95. Section 423.1970 is amended by revising paragraphs (c)(1)(ii) and (iii), and (c)(2)(ii) and (iii) to read as follows:

§ 423.1970 Right to an ALJ hearing.

* * * * *

(c) * * *

(1) * * *

(ii) The enrollee requests aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee.

(2) * * *

(ii) The enrollees request aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollees seek to aggregate involve the same prescription drugs, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollees seek to aggregate do not involve the same prescription drugs.

■ 96. Section 423.1972 is amended by revising paragraphs (a), (b), and (c)(1) to read as follows:

§ 423.1972 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the OMHA office specified in the IRE's reconsideration notice.

(b) *When to file a request.* (1) Except when an ALJ or attorney adjudicator extends the timeframe as provided in § 423.2014(d), the enrollee must file a request for a hearing within 60 calendar days of receipt of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with § 423.2020

(2) For purposes of this section, the date of receipt of the reconsideration determination is presumed to be 5 calendar days after the date of the written reconsideration determination, unless there is evidence to the contrary.

(c) * * *

(1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.1970, the ALJ or attorney adjudicator dismisses the request.

* * * * *

■ 97. Section 423.1974 is revised to read as follows:

§ 423.1974 Council review.

An enrollee who is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal as provided in § 423.2102.

§ 423.1976 [Amended]

■ 98. Section 423.1976 is amended by—

■ a. Amending paragraph (a) paragraph heading and introductory text by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

■ b. Amending paragraphs (a)(1) and (b) by removing the term "MAC" each time it appears and adding "Council" in its place.

§ 423.1978 [Amended]

■ 99. Section 423.1978(a) is amended by removing the phrase "ALJ or the MAC" and adding "ALJ or attorney adjudicator or the Council" in its place.

■ 100. Section 423.1980 is amended by revising the section heading and paragraphs (a)(1)(iii) and (iv), (a)(2) and (4), (d) paragraph heading, (d)(2) and (3), (e) paragraph heading, and (e)(2) and (3) to read as follows:

§ 423.1980 Reopening of coverage determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) * * *

(1) * * *

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

* * * * *

(4) Consistent with § 423.1978(d), the Part D plan sponsor's, IRE's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

* * * * *

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by an IRE, ALJ or attorney adjudicator, or the Council.*

* * * * *

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by an enrollee or a Part D plan sponsor.*

* * * * *

(2) An enrollee who received an ALJ's or attorney adjudicator's decision or a Part D plan sponsor may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986.

(3) An enrollee who received a Council decision or a Part D plan sponsor may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986.

§ 423.1982 [Amended]

■ 101. Section 423.1982 is amended by—

■ a. Amending paragraphs (a)(1) and (2), and (b)(1) and (2) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ b. Amending paragraphs (a)(1) and (2) and (b)(1) and (2) by removing the term "MAC" and adding "Council" in its place.

■ 102. Section 423.1984 is amended by revising paragraphs (d) and (e) to read as follows:

§ 423.1984 Effect of a revised determination or decision.

* * * * *

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding unless an enrollee submits a request for a Council review that is accepted and processed as specified in § 423.1974 and § 423.2100 through § 423.2130.

(e) *Council review.* The revision of a Council determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

* * * * *

■ 103. Section 423.1990 is amended by—

■ a. Amending paragraphs (a)(2), (b)(1) introductory text, (b)(1)(ii), and (b)(4) by removing the term "MAC" each time it appears and adding "Council" in its place

■ b. Amending paragraph (d)(2)(ii) by removing the term "MAC's" and adding "Council's" in its place.

■ c. Amending paragraph (b)(1)(i) by removing the phrase "final decision" and adding "decision" in its place and by removing the phrase "order of the ALJ" and adding "order of the ALJ or an attorney adjudicator" in its place.

■ d. Amending paragraph (b)(1)(ii) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ e. Amending paragraphs (c)(3), (4), and (5) by removing the term "ALJ hearing decision" and adding "ALJ or attorney adjudicator decision" in its place.

■ f. Revising paragraph (d)(1).

■ g. Amending paragraph (d)(2)(i) by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

■ h. Revising paragraph (h).

The revisions read as follows:

§ 423.1990 Expedited access to judicial review.

* * * * *

(d) * * *

(1) *Method and place for filing request.* The enrollee may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board, with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

* * * * *

(h) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises the enrollee in writing that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed and, if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

■ 104. Section 423.2000 is amended by revising the section heading and paragraphs (a), (b), (c), (d), (e), and (g) to read as follows:

§ 423.2000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If an enrollee is dissatisfied with an IRE's reconsideration, the enrollee may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference, or by telephone. At the hearing, the enrollee may submit evidence subject to the restrictions in § 423.2018, examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, the Part D plan sponsor, CMS, or the IRE may participate in the proceedings on a request for an ALJ hearing as specified in § 423.2010.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If an enrollee waives his or her right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

* * * * *

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding.

§ 423.2002 [Amended]

■ 105. Section 423.2002 is amended by—

■ a. Amending paragraph (a) introductory text by removing the phrase "may request" and adding "has a right to" in its place.

■ b. Amending paragraph (c) by removing the phrase "The ALJ" and adding "OMHA" in its place.

■ c. Amending paragraph (e) by removing the word "entity" and adding "office" in its place.

■ 106. Section 423.2004 is amended by revising the section heading and paragraphs (a) introductory text, (a)(1) and (4), (b), and (c) and adding paragraph (d) to read as follows:

§ 423.2004 Right to a review of IRE notice of dismissal.

(a) An enrollee has a right to have an IRE's dismissal of a request for reconsideration reviewed by an ALJ or attorney adjudicator if—

(1) The enrollee files a written request for review within 60 calendar days after receipt of the notice of the IRE's dismissal.

* * * * *

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the IRE's dismissal.

(b) If the ALJ or attorney adjudicator determines that the IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the IRE for a reconsideration in accordance with § 423.2056.

(c) If the ALJ or attorney adjudicator affirms the IRE's dismissal of a reconsideration request, he or she issues a notice of decision affirming the IRE's dismissal in accordance with § 423.2046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of an IRE's dismissal in accordance with § 423.2052(b).

■ 107. Section 423.2008 is revised to read as follows:

§ 423.2008 Parties to the proceedings on a request for an ALJ hearing.

The enrollee (or the enrollee's representative) who filed the request for hearing is the only party to the proceedings on a request for an ALJ hearing.

■ 108. Section 423.2010 is revised to read as follows:

§ 423.2010 When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS, the IRE, or the Part D plan sponsor may participate.* (1) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the proceedings on a request for an ALJ hearing upon filing a request to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

(b) *How a request to participate is made*—(1) *No notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation before it receives a notice of hearing, or when no notice is required, it must send written notice of its request to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request is not yet assigned to an ALJ or attorney adjudicator, and the enrollee, except that the request may be made orally if a request for an expedited hearing was filed and OMHA will notify the enrollee of the request to participate.

(2) *Notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation after the IRE and Part D plan sponsor receive a notice of hearing, it must send written notice of its request to participate to the ALJ and the enrollee, except that the request to participate may be made orally for an expedited hearing and OMHA will notify the enrollee of the request to participate.

(3) *Timing of request.* CMS, the IRE, and/or the Part D plan sponsor must send its request to participate—

(i) If a standard request for hearing was filed, if no hearing is scheduled, within 30 calendar days after notification that a standard request for hearing was filed;

(ii) If an expedited hearing is requested, but no hearing has been scheduled, within 2 calendar days after notification that a request for an expedited hearing was filed.

(iii) If a non-expedited hearing is scheduled, within 5 calendar days after receiving the notice of hearing; or

(iv) If an expedited hearing is scheduled, within 1 calendar day after receiving the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(c) *The ALJ's or attorney adjudicator's decision on a request to participate.* The assigned ALJ or attorney adjudicator has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate. The ALJ or attorney adjudicator must notify the entity requesting participation, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to participate within the following time frames—

(1) If no hearing is scheduled, at least 20 calendar days before the ALJ or attorney adjudicator issues a decision, dismissal, or remand;

(2) If a non-expedited hearing is scheduled, within 5 calendar days of receipt of a request to participate; or

(3) If an expedited hearing is scheduled, within 1 calendar of receipt of a request to participate.

(d) *Roles and responsibilities of CMS, the IRE, and/or the Part D plan sponsor as a participant.* (1) Participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee to the hearing.

(2) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the enrollee, but the enrollee may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS, IRE, and/or Part D plan sponsor positon papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a position paper and written testimony must be submitted—

(A) Within 14 calendar days for a standard appeal, or 1 calendar day for an expedited appeal, after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled; or

(B) No later than 5 calendar days prior to the hearing if a non-expedited hearing is scheduled, or 1 calendar day prior to the hearing if an expedited hearing is scheduled.

(ii) A copy of any position paper and written testimony that CMS, the IRE, or the Part D plan sponsor submits to OMHA must be sent to the enrollee.

(iii) If CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of its position paper or written testimony to the enrollee or fails to submit its position paper or written testimony within the time frames described in this section, the position paper or written testimony will not be considered in deciding the appeal.

(e) *Invalid requests to participate.* (1) An ALJ or attorney adjudicator may determine that a CMS, IRE, and/or Part D plan sponsor request to participate is invalid under this section if the request to participate was not timely filed or the request to participate was not sent to the enrollee.

(2) If the request to participate is determined to be invalid, the written notice of an invalid request to participate must be sent to the entity that made the request to participate and the enrollee.

(i) If no hearing is scheduled or the request to participate was made after the hearing occurred, the written notice of an invalid request to participate must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a non-expedited hearing is scheduled, the written notice of an invalid request to participate must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

(iii) If an expedited hearing is scheduled, oral notice of an invalid request to participate must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

■ 109. Section 423.2014 is revised to read as follows:

§ 423.2014 Request for an ALJ hearing or a review of an IRE dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of an IRE dismissal must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following—

(i) The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

(ii) The name, address, and telephone number of the appointed representative, as defined at § 423.560, if any.

(iii) The Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed.

(iv) The prescription drug in dispute.

(v) The plan name.

(vi) The reasons the enrollee disagrees with the IRE's reconsideration or dismissal being appealed.

(vii) A statement of whether the enrollee is aware that he or she, or the prescription for the drug being appealed, is the subject of an investigation or proceeding by the HHS Office of Inspector General or other law enforcement agencies.

(2) The enrollee must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) The enrollee must submit a statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. OMHA must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(c) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the enrollee will be provided with an opportunity to complete the request, and if an adjudication time frame applies it does not begin until the request is complete. If the enrollee fails to provide the information necessary to complete the request within the time frame provided, the enrollee's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(d) *When and where to file.* Consistent with §§ 423.1972(a) and (b), the request for an ALJ hearing after an IRE reconsideration or request for review of an IRE dismissal must be filed:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration or dismissal being appealed.

(2) With the office specified in the IRE's reconsideration or dismissal.

(i) If the request for hearing is timely filed with an office other than the office specified in the IRE's reconsideration, any applicable time frame specified in § 423.2016 for deciding the appeal begins on the date the office specified in the IRE's reconsideration or dismissal receives the request for hearing.

(ii) If the request for hearing is filed with an office, other than the office specified in the IRE's reconsideration or dismissal, OMHA must notify the enrollee of the date the request was received in the correct office and the commencement of any applicable adjudication timeframe.

(e) *Extension of time to request a hearing or review.* (1) Consistent with § 423.1972(b), if the request for hearing or review is not filed within 60 calendar days of receipt of the written IRE's reconsideration or dismissal, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. OMHA must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or review of an IRE dismissal with the office specified in the notice of reconsideration or dismissal.

(4) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of an IRE dismissal, or there is no good cause for missing the deadline to file a request for a review of an IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of an IRE dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or attorney adjudicator uses the standards set forth in § 405.942(b)(2) and (3) of this chapter.

(5) If a request for hearing is not timely filed, any applicable adjudication period in § 423.2016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(6) A determination granting a request to extend the filing deadline is not subject to further review.

■ 110. Section 423.2016 is revised to read as follows:

§ 423.2016 Timeframes for deciding an appeal of an IRE reconsideration.

(a) *Standard appeals.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(2) The adjudication period specified in paragraph (a)(1) of this section begins on the date that a timely filed request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(3) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a)(1) of this section, the remanded appeal will be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand.

(b) *Expedited appeals*—(1) *Standard for expedited appeal.* An ALJ or attorney adjudicator issues an expedited decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or an ALJ or attorney adjudicator determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to regain maximum function. An ALJ or attorney adjudicator may consider this standard as met if a lower level adjudicator has granted a request for an expedited hearing.

(2) *Grant of a request.* If an ALJ or attorney adjudicator grants a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make the decision to grant an expedited appeal within 5 calendar days of receipt of the request for an expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) *Denial of a request.* If an ALJ or attorney adjudicator denies a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make this decision within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that an ALJ or attorney adjudicator will process the enrollee's request using the 90 calendar day timeframe for non-expedited appeals; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 calendar days after the oral notice.

(4) *Decision not appealable.* A decision on a request for expedited hearing may not be appealed.

(5) *Time frame for adjudication.* (i) If an ALJ or attorney adjudicator accepts a request for expedited hearing, an ALJ or attorney adjudicator issues a written decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's written notice of reconsideration, unless the 10 calendar day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely provided, the date that an ALJ or attorney adjudicator grants any extension to the filing deadline.

(6) *Time frame for Council remands.* If the Council remands a case and the case was subject to an adjudication time frame under paragraph (b)(5) of this section, the remanded appeal will be subject to the same adjudication timeframe beginning on the date that OMHA receives the Council remand, if the standards for an expedited appeal continue to be met. If the standards for an expedited appeal are no longer met, the appeal will be subject to the adjudication time frame for a standard appeal.

(c) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the enrollee may waive the adjudication period specified in paragraphs (a)(1) and (b)(5) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the enrollee.

(2) The adjudication periods specified in paragraphs (a)(1) and (b)(5) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the matters at issue ordered by a court or tribunal of competent jurisdiction;

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an enrollee.

■ 111. Section 423.2018 is revised to read as follows:

§ 423.2018 Submitting evidence.

(a) *All appeals.* An enrollee must submit any written or other evidence that he or she wishes to have considered.

(1) An ALJ or attorney adjudicator will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination was made.

(2) An ALJ or attorney adjudicator will remand a case to the Part D IRE where an enrollee wishes evidence on his or her change in condition after the coverage determination to be considered.

(b) *Non-expedited appeals.* (1) Except as provided in this paragraph, a represented enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing by the date specified in the request for hearing in accordance with § 423.2014(a)(2), or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(3) The requirements of paragraph (b) of this section do not apply to unrepresented enrollees.

(c) *Expedited appeals.* (1) Except as provided in this section, an enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing by the date specified in the request for hearing pursuant to § 423.2014(a)(2), or, if an expedited hearing is scheduled, within 2 calendar days of receiving the notice of the expedited hearing.

(2) If an enrollee submits written or other evidence later than 2 calendar days after receiving the notice of expedited hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 2 calendar days after receipt of the notice of expedited hearing and the day the evidence is received.

(d) *When this section does not apply.* The requirements of paragraphs (b) and (c) of this section do not apply to oral testimony given at a hearing.

■ 112. Section 423.2020 is amended by

■ a. Revising paragraphs (b), (c), (d), and (e)(3) and (4).

■ b. Adding paragraphs (g)(3)(vii) and (viii).

■ c. Revising paragraphs (h), (i) paragraph heading, and (i)(1), (2), (4), and (5).

■ d. Adding paragraph (j).

The revisions and additions read as follows:

§ 423.2020 Time and place for a hearing before an ALJ.

* * * * *

(b) *Determining how appearances are made.* (1) *Appearances by unrepresented enrollees.* The ALJ will direct that the appearance of an unrepresented enrollee who filed a request for hearing be conducted by video-teleconferencing if the ALJ finds that video-teleconferencing technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented enrollee.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by represented enrollees.* The ALJ will direct that the appearance of an individual, other than an unrepresented enrollee who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by video-teleconferencing if he or she determines that video-teleconferencing is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to the enrollee, the Part D plan sponsor that issued the coverage determination, and the IRE that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require the enrollee to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS, the IRE, or the Part D plan sponsor that requests to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing,

(d) *An enrollee's right to waive a hearing.* An enrollee may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 423.2038(b).

(1) As specified in § 423.2000, an ALJ may require the enrollee to attend a hearing if it is necessary to decide the case.

(2) If an ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may still hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In those cases, the ALJ would give the enrollee the opportunity to appear when the testimony is given but may hold the hearing even if the enrollee decides not to appear.

* * * * *

(e) * * *

(3) The objection must be in writing except for an expedited hearing when the objection may be provided orally, and except that the enrollee may orally request that a non-expedited hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral objections to the time and place of a hearing in writing and maintain the documentation in the case files.

(4) The ALJ may change the time or place of the hearing if the enrollee has good cause.

* * * * *

(g) * * *

(3) * * *

(vii) The enrollee or enrollee's representative has a prior commitment that cannot be changed without significant expense.

(viii) The enrollee or enrollee's representative asserts he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the enrollee for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 423.2016.

(i) *An enrollee's request for an in-person or video-teleconferencing hearing.* (1) If an unrepresented enrollee objects to a video-teleconferencing hearing or to the ALJ's offer to conduct a hearing by telephone, or a represented enrollee who filed the request for hearing objects to a telephone or video-teleconferencing hearing, the enrollee or the enrollee's representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a video-teleconferencing or an in-person hearing.

(2) The enrollee must state the reason for the objection and state the time and/or place he or she wants an in-person or video-teleconferencing hearing to be held.

* * * * *

(4) When an enrollee's request for an in-person or video-teleconferencing hearing is granted and an adjudication time frame applies in accordance with § 423.2016, the ALJ issues a decision, dismissal, or remand to the IRE within the adjudication time frame specified in § 423.2016 (including any applicable extensions provided in this subpart), unless the enrollee requesting the hearing agrees to waive such adjudication timeframe in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee, upon a finding of good cause and will reschedule the hearing for a time and place when the enrollee may appear in person or by video-teleconference before the ALJ.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with § 423.2022(a)(2).

■ 113. Section 423.2022 is revised to read as follows:

§ 423.2022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* (1) After the ALJ sets the time and place of the hearing, the notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the enrollee and other potential participants, as provided in § 423.2020(c) at their last known addresses, or given by personal service, except to an enrollee or other potential participant who indicates in writing that he or she does not wish to receive this notice.

(2) The notice is mailed, transmitted, or served at least 20 calendar days before the hearing, except for expedited hearings where written notice is mailed, transmitted, or served at least 3 calendar days before the hearing, unless the enrollee or other potential participant agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the non-expedited hearing or 3 calendar days before the expedited hearing. For expedited hearings, the ALJ may orally provide notice of the hearing to the enrollee and other potential participants but oral notice must be followed by an equivalent written notice within 1 calendar day of the oral notice.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in the enrollee's favor and that were specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 423.2032.

(2) The notice will inform the enrollee that he or she may designate a person to represent him or her during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the enrollee fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The enrollee will also be told if his or her appearance or that of any other witness is scheduled by video-teleconferencing, telephone, or in person. If the ALJ has scheduled the enrollee to appear at the hearing by video-teleconferencing, the notice of hearing will advise that the scheduled place for the hearing is a video-teleconferencing site and explain what it means to appear at the hearing by video-teleconferencing.

(5) The notice advises the enrollee that if he or she objects to appearing by video-teleconferencing or telephone, and wishes instead to have his or her hearing at a time and place where he or she may appear in person before the ALJ, he or she must follow the procedures set forth at § 423.2020(i) for notifying the ALJ of his or her objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the enrollee or his or her representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the enrollee for an explanation.

(2) If the enrollee states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the enrollee and in accordance with OMHA procedures.

(3) The enrollee may request that the ALJ reschedule the hearing in accordance with § 423.2020(e).

■ 114. Section 423.2024 is amended by—

■ a. Amending paragraph (a) by removing the phrase "The ALJ hearing office" and adding "OMHA" in its place.

■ b. Revising paragraph (c) to read as follows:

§ 423.2024 Objections to the issues.

* * * * *

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

■ 115. Section 423.2026 is revised to read as follows:

§ 423.2026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator may not adjudicate an appeal if he or she is prejudiced or partial to the enrollee or has any interest in the matter pending for decision.

(b) If an enrollee objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the enrollee must notify the ALJ within 10 calendar days of the date of the notice of hearing if a non-expedited hearing is scheduled, except for expedited hearings in which the enrollee must submit written or oral notice no later than 2 calendar days after the date of the notice of hearing, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator must document all oral objections in writing and maintain the documentation in the case files. The ALJ or attorney adjudicator considers the enrollee's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the enrollee may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 423.2100 through § 423.2130. The Council will then consider whether the decision or dismissal should be revised or, if applicable, a new hearing held before another ALJ.

(d) If the enrollee objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by 14 calendar days for a standard appeal, or 2 calendar days for an expedited appeal.

■ 116. Section 423.2030 is revised to read as follows:

§ 423.2030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the enrollee and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) The ALJ fully examines the issues, questions the enrollee and other witnesses, and may accept evidence that is material to the issues consistent with § 423.2018.

(2) The ALJ may limit testimony and argument at the hearing that are not relevant to an issue before the ALJ, or that address an issue before the ALJ for which the ALJ determines he or she has sufficient information or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the enrollee or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that the enrollee or enrollee's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing, the ALJ may excuse the enrollee or representative from the hearing and continue with the hearing to provide the participants with an opportunity to offer testimony and/or argument. If an enrollee or representative was excused from the hearing, the ALJ will provide the enrollee or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the enrollee or representative may request a recording of the hearing in accordance with § 423.2042 and respond in writing to any statements made by participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing.

(d) *Effect of new evidence on adjudication period.* If an enrollee, other than an unrepresented enrollee in a standard appeal, submits evidence pursuant to paragraph (b) or (c), and an adjudication period applies to the appeal, the adjudication period specified in § 423.2016 is extended in accordance with § 423.2018(b) or (c), as applicable.

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with § 423.2022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the continuance and an adjudication time frame applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 423.2022, except that the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

■ 117. Section 423.2032 is revised to read as follows:

§ 423.2032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the appealed matter specified in the request for hearing that were brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in an enrollee's favor.

(b) *New issues*—(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS, the IRE, or the Part D plan sponsor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS, the IRE, or the Part D plan sponsor for the first time to the ALJ. The ALJ or the enrollee may raise a new issue; however, the ALJ may only consider a new issue relating to a determination or appealed matter specified in the request for hearing, including a favorable portion of a determination or appealed matter specified in the request for hearing, if its resolution could have a material impact on the appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the enrollee about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the enrollee will have at least 10 calendar days in standard appeals or 2 calendar days in expedited appeals after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding coverage determinations to a pending appeal.* A coverage determination on a drug that was not specified in a request for hearing may only be added to pending appeal if the coverage determination was adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on the reconsideration in accordance with § 423.2014(e).

■ 118. Section 423.2034 is revised to read as follows:

§ 423.2034 Requesting information from the IRE.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, the information may be requested from the IRE that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed issues can only be provided by CMS, the IRE, and/or the Part D plan sponsor.

(2) "Can be provided only by CMS, the IRE, and/or the Part D plan sponsor" means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor Web site or information in an official CMS or HHS publication.

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The IRE has 15 calendar days for standard appeals, or 2 calendar days for expedited appeals, after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or the Part D plan sponsor.

(d) If an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the date of the request for information and the date the IRE responds to the request or 20 calendar days after the date of the request for standard appeals, or 3 calendar days after the date of the request for expedited appeals, whichever occurs first.

§ 423.2036 [Amended]

■ 119. Section 423.2036 is amended by—

■ a. Amending paragraph (b)(1) introductory text by removing the phrase "send the ALJ" and adding "submit to OMHA" in its place.

■ b. Amending paragraph (b)(1)(ii) by removing the phrase "The ALJ hearing office" and adding "OMHA" in its place.

■ c. Removing paragraph (d).

■ d. Redesignating paragraph (g) as new paragraph (d).

■ e. Amending paragraphs (f)(2), (f)(3) introductory text, and (f)(3) (i), (ii), and (iii) by removing the term "MAC" and adding "Council" in its place.

■ f. Amending paragraph (f)(2) by removing the term "MAC's" and adding "Council's" in its place.

■ 120. Section 423.2038 is revised to read as follows:

§ 423.2038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the enrollee(s) on every issue, the ALJ or attorney adjudicator may issue a decision without giving the enrollee(s) prior notice and without an ALJ conducting a hearing. The notice of the decision informs the enrollee(s) that he or she has the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Enrollee does not wish to appear.* (1) The ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available. OMHA must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS, the IRE, and/or the Part D plan sponsor submits a written statement or makes an oral statement at a hearing indicating the drug should be covered or payment may be made, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the enrollee on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

■ 121. Section 423.2040 is revised to read as follows:

§ 423.2040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of the enrollee to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) For non-expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing, of the time, place, and purpose of the conference at least 2 calendar days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) All oral requests not to receive written notice of the conference must be documented in writing and the documentation must be made part of the administrative record.

(e) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice, if the enrollee consents to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(f) The ALJ issues an order to the enrollee and all participants who attended the conference stating all agreements and actions resulting from the conference. If the enrollee does not object within 10 calendar days of receiving the order for non-expedited hearings or 1 calendar day for expedited hearings, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on the enrollee.

■ 122. Section 423.2042 is revised to read as follows:

§ 423.2042 The administrative record.

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conference and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including but not limited to duplicative evidence submitted by the enrollee.

(3) An enrollee may request and receive a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if an enrollee seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, an enrollee may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. The enrollee may be asked to pay the costs of providing these items.

(2) If an enrollee requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 423.2016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the enrollee's response.

(3) If the enrollee requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the enrollee is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the enrollee obtains consent from the individual.

■ 123. Section 423.2044 is revised to read as follows:

§ 423.2044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the

issue(s) may be more efficiently decided if the appeals are consolidated for hearing. In considering the enrollee's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an enrollee to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an enrollee to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§ 423.2020 and 423.2022.

(b) *Consolidated decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the enrollee or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same enrollee, unless multiple enrollees aggregated appeals to meet the amount in controversy requirement in accordance with § 423.1970 and the enrollees have all authorized disclosure of information to the other enrollees.

■ 124. Section 423.2046 is revised to read as follows:

§ 423.2046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(i) The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions.

(ii) A copy of the decision should be mailed or otherwise transmitted to the enrollee at his or her last known address.

(iii) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination.

(2) *Content of the notice.* The decision must be provided in a manner calculated to be understood by an enrollee and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's or attorney adjudicator's decision is a new coverage determination under § 423.566.

(b) *Decisions on requests for review of an IRE dismissal*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of an IRE dismissal, or the dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the IRE's dismissal. OMHA mails or otherwise transmits a copy of the decision to the enrollee.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by an enrollee and must include—

(i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to the enrollee at his or her last known address.

■ 125. Section 423.2048 is revised to read as follows:

§ 423.2048 The effect of an ALJ's or attorney adjudicator's decision.

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding unless—

(1) An enrollee requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 423.2110, and the Council issues a final decision or remand order;

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 423.1980;

(3) The expedited access to judicial review process at § 423.1990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 423.2138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of an IRE dismissal is binding on the enrollee unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures explained in § 423.1980.

§ 423.2050 [Amended]

■ 126. Section 423.2050 is amended by—

■ a. Amending the section heading by removing the phrase "an ALJ" and adding "OMHA" in its place.

■ b. Amending the text of the section by removing the phrase "pending before an ALJ" and adding "pending before OMHA" in its place, and by removing the term "the ALJ" and adding "OMHA" in its place.

■ c. Amending the section heading and the text of the section by removing the term "MAC" each time it appears and adding "Council" in its place.

■ 127. Section 423.2052 is revised to read as follows:

§ 423.2052 Dismissal of a request for a hearing before an ALJ or request for review of an IRE dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the enrollee that requested the hearing nor the enrollee's representative appears at the time and place set for the hearing, if—

(i) The enrollee was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the enrollee acknowledged the notice of hearing, and the enrollee does not contact the ALJ within 10 calendar days after the hearing for non-expedited hearings and 2 calendar days after the hearing for expedited hearings, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the enrollee acknowledged the notice of hearing, the ALJ sends a notice to the enrollee at his or her last known address asking why the enrollee did not appear, and the enrollee does not respond to the ALJ's notice within 10 calendar days for non-expedited hearings or within 2 calendar days for expedited hearings after receiving the notice, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing. For expedited hearings, an enrollee may submit his or her response orally to the ALJ.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) the enrollee may have.

(2) The person requesting a hearing has no right to it under § 423.2002.

(3) The enrollee did not request a hearing within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 423.2014(e).

(4) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(5) The ALJ or attorney adjudicator dismisses a hearing request entirely or refuses to consider any one or more of the issues because an IRE, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the enrollee's rights on the same facts and on the same issue(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The enrollee abandons the request for hearing. An ALJ or attorney adjudicator may conclude that an enrollee has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the enrollee after making reasonable efforts to do so.

(7) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(b) *Dismissal of request for review of IRE dismissal.* An ALJ or attorney adjudicator dismisses a request for review of an IRE dismissal under any of the following conditions:

(1) The enrollee has no right to a review of the IRE dismissal under § 423.2004.

(2) The enrollee did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 423.2014(e).

(3) The enrollee died while the request for review was pending and the request was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(4) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if the enrollee asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of an IRE dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the enrollee is withdrawing the request for hearing or review of the IRE dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of an enrollee files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the enrollee of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the enrollee at his or her last known address. The written notice provides that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 6 months of the date of the notice of dismissal.

■ 128. Section 423.2054 is revised to read as follows:

§ 423.2054 Effect of dismissal of a request for a hearing or request for review of an IRE's dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 423.2108(b), or vacated by the ALJ or attorney adjudicator under § 423.2052(e).

(b) The dismissal of a request for review of an IRE dismissal of a request for reconsideration is binding and not subject to further review unless vacated by the ALJ or attorney adjudicator under § 423.2052(e).

■ 129. Section 423.2056 is added to read as follows:

§ 423.2056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed coverage determination in accordance with § 423.2034, and the IRE, CMS, or Part D plan sponsor does not furnish the copy within the time frame specified in § 423.2034, an ALJ or attorney adjudicator may issue a remand directing the IRE or Part D plan sponsor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the IRE does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a

remand directing the IRE to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the IRE or Part D plan sponsor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the IRE issued a reconsideration and no redetermination was made with respect to the issue under appeal or the request for redetermination was dismissed, the reconsideration will be remanded to the IRE, or its successor, to re-adjudicate the request for reconsideration.

(c) *Requested remand*—(1) *Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the enrollee and CMS, the IRE, or the Part D plan sponsor may jointly request a remand of the appeal to the IRE. The request must include the reasons why the appeal should be remanded, and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding an IRE's dismissal of a request for reconsideration.* Consistent with § 423.2004(b), an ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that an IRE's dismissal of a request for reconsideration was in error.

(e) *Consideration of change in condition.* The ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that the enrollee wants evidence on his or her change in condition after the coverage determination to be considered in the appeal.

(f) *Notice of a remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the enrollee at his or her last known address, and CMS, the IRE, and/or the Part D plan sponsor if a request to be a participant was granted by the ALJ or attorney adjudicator. The notice states that there is a right to request that the Chief ALJ or a designee review the remand.

(g) *Review of remand.* Upon a request by the enrollee or CMS, the IRE, or the Part D plan sponsor filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review.

■ 130. Section 423.2058 is added to read as follows:

§ 423.2058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with § 423.2056(g).

§ 423.2062 [Amended]

■ 131. Section 423.2062 is amended by—

■ a. Amending the section heading and paragraphs (a) and (b) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending paragraph (a) by removing the term "ALJs" and adding "ALJs and attorney adjudicators" in its place.

■ c. Amending paragraph (b) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.

■ 132. Section 423.2063 is revised to read as follows:

§ 423.2063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare program, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the CMS Administrator. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, and on all HHS components that adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter are binding on all CMS components, and all HHS components that adjudicate matters under the jurisdiction of CMS.

■ 133. Section 423.2100 is revised to read as follows:

§ 423.2100 Medicare Appeals Council review: general.

(a) Consistent with § 423.1974, the enrollee may request that the Council review an ALJ's or attorney adjudicator's decision or dismissal.

(b) When the Council reviews an ALJ's or attorney adjudicator's written decision, it undertakes a de novo review.

(c) The Council issues a final decision, dismissal order, or remands a case to the ALJ or attorney adjudicator no later than the end of the 90 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 90 calendar day period is extended as provided in this subpart or the enrollee requests expedited Council review.

(d) If an enrollee requests expedited Council review, the Council issues a final decision, dismissal order or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 10 calendar day period is extended as provided in this subpart.

■ 134. Section 423.2102 is revised to read as follows:

§ 423.2102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) An enrollee may request Council review of a decision or dismissal issued by an ALJ or attorney adjudicator if the enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's written decision or dismissal.

(2) An enrollee may request that Council review be expedited if the appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(i) If an enrollee is requesting that the Council review be expedited, the enrollee submits an oral or written request within 60 calendar days after the receipt of the ALJ's or attorney adjudicator's written decision or dismissal. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(ii) The Council must document all oral requests for expedited review in writing and maintain the documentation in the case files.

(3) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's written decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(4) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) An enrollee requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing or, for expedited reviews, in writing or oral. The Council must document all oral requests in writing and maintain the documentation in the case file.

(2) The request explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at § 405.942(b)(2) and (3) of this chapter.

(c) An enrollee does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to an IRE, or an ALJ's or attorney adjudicator's affirmation of an IRE's dismissal of a request for reconsideration, or dismissal of a request to review an IRE dismissal.

§ 423.2106 [Amended]

■ 135. Section 423.2106 is amended by—

■ a. Removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ b. Removing the term "ALJ's" each time it appears and adding "ALJ's or attorney adjudicator's" in its place.

■ c. Removing the term "MAC" each time it appears and adding "Council" in its place.

■ d. Removing the term "MAC's" and adding "Council's" in its place.

§ 423.2108 [Amended]

■ 136. Section 423.2108 is amended by—

■ a. Amending paragraphs (a), (b), and (c) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ b. Amending paragraphs (a) and (d)(2)(iii) by removing the term "ALJ's" each time it appears and adding "ALJ's or attorney adjudicator's" in its place.

■ c. Amending the section heading and paragraphs (a), (b), (c), (d)(1), (d)(2) introductory text, (d)(3) introductory text, and (d)(3)(ii) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ d. Amending paragraph (a) by removing the term "MAC's" and adding "Council's" in its place.

■ e. Amending the paragraph heading and text of paragraph (b) by removing the phrase "ALJ's dismissal" and adding "ALJ's or attorney adjudicator's dismissal of a request for a hearing" in its place.

■ 137. Section 423.2110 is revised to read as follows:

§ 423.2110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or the IRE may refer a case to the Council for it to consider reviewing under this authority any time within 60 calendar days after the date of an ALJ's or attorney adjudicator's written decision or dismissal.

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the Council if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the appeal or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the Council take own motion review of a case if—

(i) CMS or the IRE participated or requested to participate in the appeal at the OMHA level; and

(ii) In CMS' or the IRE's view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' or the IRE's referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's written decision or dismissal is issued.

(i) The written referral will state the reasons why CMS or the IRE believes that the Council should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the OMHA Chief ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice.

(iv) An enrollee submitting comments to the Council must send the comments to CMS or the IRE.

(c) *Standard of review*—(1) *Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the OMHA level.* If CMS or the IRE participated or requested to participate in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the OMHA proceedings.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(d) *Council's action.* (1) If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings, or may dismiss a hearing request.

(3) The Council must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The Council may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the Council declines to review a decision or dismissal on its own motion, the ALJ's or attorney adjudicator's decision or dismissal is binding.

§ 423.2112 [Amended]

■ 138. Section 423.2112 is amended by—

■ a. Amending paragraphs (a)(1), (b), and (c) by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

■ b. Amending paragraph (b) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ c. Amending paragraphs (a)(1) and (3), and (c) by removing the term "MAC" and adding "Council" in its place.

§ 423.2114 [Amended]

■ 139. Section 423.2114 is amended in the introductory text and paragraph (b) by removing the term "MAC" each time it appears and adding "Council" in its place.

§ 423.2116 [Amended]

■ 140. Section 423.2116 is amended by—

■ a. Removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Removing the term "MAC's" and adding "Council's" in its place.

■ c. Removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

§ 423.2118 [Amended]

■ 141. Section 423.2118 is amended by—

■ a. Removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Removing the term "MAC's" and adding "Council's" in its place.

■ c. Removing the phrase "ALJ hearing" and adding "ALJ's or attorney adjudicator's action" in its place.

■ d. Removing the phrase "the exhibits list" and adding "any index of the administrative record" in its place.

■ e. Removing the term "CD" and adding "audio recording" in its place.

§ 423.2120 [Amended]

■ 142. Section 423.2120 is amended by removing the term "MAC" each time it appears and adding "Council" in its place.

§ 423.2122 [Amended]

■ 143. Section 423.2122 is amended by—

■ a. Amending the section heading and paragraphs (a) paragraph heading, (a)(1), (2), and (3), (b) introductory text, (b)(1) and (2), and (c)(1), (2), (3), and (4) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending paragraphs (a) paragraph heading and (a)(1) by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

■ c. Amending paragraph (a)(1) by removing the term "ALJ level" and adding "OMHA level" in its place.

■ d. Amending paragraph (a)(1) by removing the term "hearing decision" and adding "ALJ's or attorney adjudicator's decision" in its place.

■ e. Amending paragraphs (a)(1) and (2) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ f. Amending paragraph (a)(2) by removing the term "hearing record" and adding "administrative record" in its place.

■ g. Amending paragraph (c)(3) by removing the term "MAC's" and adding "Council's" in its place.

§ 423.2124 [Amended]

■ 144. Section 423.2124 is amended in the introductory text and paragraphs (a), (b), (c), (d), and (e) by removing the term "MAC" each time it appears and adding "Council" in its place.

§ 423.2126 [Amended]

■ 145. Section 423.2126 is amended by—

■ a. Amending the section heading and paragraphs (a) paragraph heading, (a)(1), (2), and (3), (a)(4) paragraph heading, (a)(4)(i) and (ii), (a)(5) paragraph heading, (a)(5)(i) and (ii), and (b) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending paragraphs (a) paragraph heading, (a)(1), (2), and (3), (a)(4) paragraph heading, and (a)(5)(ii) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.

■ c. Amending paragraph (a)(2) by removing the term "MAC's and adding "Council's" in its place.

■ d. Amending paragraph (a)(5)(ii) by adding "if applicable" after the word "rehearing".

§ 423.2128 [Amended]

■ 146. Section 423.2128 is amended by—

■ a. Amending the section heading and paragraphs (a), (b), and (c) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending paragraph (a) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

■ c. Amending paragraph (b) by removing the phrase "ALJ hearing decision" and adding "ALJ or attorney adjudicator decision" in its place.

§ 423.2130 [Amended]

■ 147. Section 423.2130 is amended in the section heading and text by removing the term "MAC's" each time it appears and adding "Council's" in its place.

§ 423.2134 [Amended]

■ 148. Section 423.2134 is amended in paragraphs (b)(3) and (c) by removing the term "MAC" and adding "Council" in its place.

§ 423.2136 [Amended]

■ 149. Section 423.2136 is amended by—

■ a. Amending paragraphs (a) and (c)(3) by removing the term "MAC" and adding "Council" in its place.

■ b. Amending paragraph (c)(2) by removing the term "MAC's" and adding "Council's" in its place.

■ c. Amending paragraph (c)(3) by removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

§ 423.2138 [Amended]

■ 150. Section 423.2138 is amended by—

■ a. Removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Removing the term "ALJ" and adding "ALJ or attorney adjudicator" in its place.

§ 423.2140 [Amended]

■ 151. Section 423.2140 is amended by—

■ a. Amending the section heading and paragraphs (a)(1), (2), and (3), (b)(1), (b)(2) introductory text, (b)(2)(ii), (b)(3) and (4), (c) paragraph heading, (c)(1), (3), and (4), and (d) by removing the term "MAC" each time it appears and adding "Council" in its place.

■ b. Amending the section heading and paragraphs (a)(1), (2), and (3), (b) paragraph heading, (b)(1), (b)(2) introductory text, (b)(2)(i), (b)(3) and (4), (c)(1) and (4), and (d) by removing the term "ALJ" each time it appears and adding "ALJ or attorney adjudicator" in its place.

■ c. Amending paragraph (d) by removing the term "ALJ's" and adding "ALJ's or attorney adjudicator's" in its place.

PART 478—RECONSIDERATIONS AND APPEALS

■ 152. The authority citation for part 478 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 153. Section 478.14(c)(2) is amended by removing the phrase "part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B" and adding "part 405, subpart I of this chapter for determinations under Medicare Part A and Part B" in its place.

■ 154. Section 478.40 is amended by revising paragraphs (a) and (c) to read as follows:

§ 478.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a QIO reconsidered determination may request a hearing by an administrative law judge (ALJ) of the Office of Medicare Hearings and Appeals (OMHA).

* * * * *

(c) *Governing provisions.* The provisions of subpart I of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart or implement statutory provisions that are not also applicable under section 1155 of the Social Security Act. References in subpart I to initial determinations made by a Medicare contractor and reconsiderations made by a QIC should be read to mean initial determinations and reconsidered determinations made by a QIO.

■ 155. Section 478.42 is revised to read as follows:

§ 478.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 478.40 must submit a written request to the OMHA office identified in the notice of the QIO reconsidered determination.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination, unless the time is extended for good cause as provided in § 478.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be 5 calendar days after the date on the notice, unless there is evidence to the contrary.

(3) A request is considered filed on the date it is received by OMHA.

■ 156. Section 478.44 is revised to read as follows:

§ 478.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with § 405.1006(d) and (e) of this chapter. When two or more appellants submit a request for hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with § 405.1006(d) and (e) of this chapter.

(b) If the ALJ or attorney adjudicator determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, or attorney adjudicator notifies the parties that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least $200.

(c) At the end of the 15-day period, if an ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties and the QIO that the QIO reconsidered determination is conclusive for Medicare payment purposes.

■ 157. Section 478.46 is revised to read as follows:

§ 478.46 Medicare Appeals Council and judicial review.

(a) The circumstances under which the Medicare Appeals Council (Council) will review an ALJ's or attorney adjudicator's decision or dismissal are the same as those set forth at §§ 405.1102 (“Request for Council review when ALJ or attorney adjudicator issues decision or dismissal”) and 405.1110 (“Council reviews on its own motion”) of this chapter.

(b) If $2,000 or more is in controversy, a party may obtain judicial review of a Council decision, or an ALJ's or attorney adjudicator's decision if a request for review by the Council was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Council decision or denial.

■ 158. Section 478.48 is amended by revising the section heading and paragraphs (b) and (c) to read as follows:

§ 478.48 Reopening and revision of a reconsidered determination or a decision.

* * * * *

(b) *ALJ or attorney adjudicator and Council Reopening—Applicable procedures.* The ALJ or attorney adjudicator, or the Council, whichever made the decision, may reopen and revise the decision in accordance with the procedures set forth in § 405.980 of this chapter, which concerns reopenings and revised decisions under subpart I of part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or attorney adjudicator, or the Council may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

Approved: June 8, 2016.

Sylvia Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–15192 Filed 6–28–16; 4:15 pm]

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Part IV

Environmental Protection Agency

40 CFR Part 52

Approval, Disapproval and Promulgation of Air Quality Implementation Plans; Partial Approval and Partial Disapproval of Air Quality Implementation Plans and Federal Implementation Plan; Utah; Revisions To Regional Haze State Implementation Plan; Federal Implementation Plan for Regional Haze; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2015–0463; FRL–9947–42–Region 8]

Approval, Disapproval and Promulgation of Air Quality Implementation Plans; Partial Approval and Partial Disapproval of Air Quality Implementation Plans and Federal Implementation Plan; Utah; Revisions to Regional Haze State Implementation Plan; Federal Implementation Plan for Regional Haze

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is partially approving and partially disapproving a State Implementation Plan (SIP) revision submitted by the State of Utah on June 4, 2015 to implement the regional haze program pursuant to section 169A of the Clean Air Act (CAA or Act). The State's SIP revisions would establish an alternative to best available retrofit technology (BART) controls that would otherwise be required to control nitrogen oxides (NO_X) at PacifiCorp's Hunter and Huntington power plants. The June 2015 SIP revision also includes BART determinations for particulate matter with an aerodynamic diameter of less than 10 micrometers (PM_{10}) at these power plants and provisions for making the NO_X and PM_{10} BART emission limits federally enforceable. The CAA requires states to prevent any future and remedy any existing man-made impairment of visibility in national parks and wilderness areas designated as Class I areas. Air emissions from the four electric generating units (EGUs) at the two plants affected by this action cause or contribute to visibility impairment at nine Class I areas including Grand Canyon, Arches, Black Canyon, Bryce Canyon, Canyonlands, Capitol Reef, Mesa Verde and Zion National Parks and Flat Tops Wilderness Area. The EPA is finalizing the option in our January 14, 2016 co-proposal to partially approve and partially disapprove the June 2015 SIP revision and is promulgating a Federal Implementation Plan (FIP) to address the deficiencies identified in our proposed partial disapproval of Utah's regional haze SIP. The EPA is not taking any final action on a related October 20, 2015 SIP revision. The State retains its authority to submit a revised state plan consistent with CAA and Regional Haze Rule (RHR) requirements. An approvable SIP submission will result in the modification or withdrawal of the FIP.

DATES: This final rule is effective August 4, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2015–0463. All documents in the docket are listed on the *www.regulations.gov* Web site. Publicly available docket materials are available either electronically through *www.regulations.gov,* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if, at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Gail Fallon, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado, 80202–1129, (303) 312–6281, *Fallon.Gail@epa.gov.*

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I. Introduction

The purpose of federal and state regional haze plans is to achieve the national goal, declared by Congress, of restoring and protecting visibility at 156 federal Class I areas across the United States, most of which are national parks and wilderness areas with scenic vistas enjoyed by the American public. The national goal, as described in CAA section 169A, is the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I federal areas where such impairment results from man-made air pollution. States are required to submit SIPs that, among other things, ensure reasonable progress toward the national goal of remedying anthropogenic visibility impairment in federal Class I areas. Arizona, Colorado, and Utah have a wealth of such areas that are impacted by the Hunter and Huntington power plants, including Grand Canyon, Arches, Black Canyon, Bryce Canyon, Canyonlands, Capitol Reef, Mesa Verde and Zion National Parks and Flat Tops Wilderness Area. The four units at the two power plants that are subject to the CAA BART requirements are large sources of NO_X,[1] and the NO_X emissions from these plants affect visibility[2] at some of the countries' most beloved Class I areas that are visited by millions of Americans. The CAA requires that such sources install and operate controls to limit visibility impairing pollutants; in this instance there are very cost-effective controls available for these units, which will operate for many years into the future.

We proposed action on Utah's June 4, 2015 and October 20, 2015 regional haze SIP submittals addressing NO_X and PM_{10} BART requirements on January 14, 2016.[3] The EPA conducted a public hearing for our proposed action in Salt Lake City, Utah on January 26, 2016. Our public comment period closed on March 14, 2016.

In this action, we are partially approving and partially disapproving the SIP submittal submitted by Utah on June 4, 2015, and taking no action on the State's October 20, 2015 SIP submittal. These submittals include actions intended to satisfy the State's obligations for the regional haze program's first planning period, including the obligation to submit a SIP containing emission limitations representing BART for NO_X and PM for each of the four subject-to-BART sources of visibility-impairing emissions. We are also promulgating a FIP to address the deficiencies we have identified in the portions of the SIP submittal that we are disapproving.

Utah's SIP submittal was to address the BART requirements for NO_X in part through reliance on a BART alternative program under 40 CFR 51.308(e)(2), which allows a state to implement such a BART alternative when the clear weight of the evidence demonstrates that it achieves greater reasonable progress than BART.[4] Specifically, rather than installing and operating BART controls for its four subject-to-BART electric generating units (EGUs), Utah's SIP submittal relied on an alternative program, which included the following: (1) The installation of upgraded combustion controls between 2006 and 2014 at the four BART units plus an additional EGU at PacifiCorp's Hunter plant; and (2) the shutdown of the Carbon plant, a non-BART source, to meet the BART requirements for emissions of NO_X. To meet its PM BART requirements, Utah's SIP submittal included the most stringent control technology at each of the four subject-to-BART EGUs. We provided a detailed explanation of the contents of Utah's June and October 2015 submittals along with an overview of earlier Utah regional haze submittals and EPA's actions on these earlier submittals in sections IV and III.E, respectively, of our proposed rule.[5]

EPA takes very seriously a decision to disapprove any state plan. Our intention is to approve a state's exercise of discretion if it can be supported. However, to approve a state plan EPA must be able to find that the plan is consistent with the requirements of the CAA and EPA's regulations. Although these are largely fact-based decisions, we focus strongly on consistently applying the regional haze requirements across this national program. After carefully considering the comments on our proposal, we determined that there is only one permissible outcome. Therefore, for the reasons described in our proposal and in this action, we find that the State's NO_X BART Alternative for the power plants is not consistent with the applicable statutory and regulatory requirements. As a result, EPA has determined that final disapproval is the only path that is consistent with the Act.

Although we are promulgating a federal plan, the State retains its authority to submit a revised state plan consistent with CAA and Regional Haze Rule requirements. If we determine that the SIP revision is approvable, regardless of whether or not its terms match those of our final FIP, we would propose to approve such a SIP revision. An approvable SIP submission will result in the modification or withdrawal of the FIP.[6]

A. Our Co-Proposals

When we reviewed the Utah regional haze SIP, we noted that some of the metrics the State included in its weight-of-evidence analysis presented to support the NO_X BART Alternative appear to support a conclusion that the BART Alternative achieves greater reasonable progress than BART (*i.e.*, selective catalytic reduction (SCR) technology at the four BART units at Hunter and Huntington). However, we also noted that several other metrics in the State's analyses did not appear to support a conclusion that the BART Alternative achieves greater reasonable progress. The collection of information before EPA at the time of proposal presented a close call for us to decide whether to approve or disapprove the State's BART Alternative. Therefore, to allow all interested parties an opportunity to comment on either approach, we proposed and solicited comment on two possible conclusions and courses of action: (1) The State's submittal for NO_X BART meets the test under 40 CFR 51.308(e)(2)(i)(E) and we approve the BART Alternative; or (2) the State's submittal falls short of meeting this test and we disapprove the BART Alternative and promulgate a FIP for NO_X BART. We requested comment on all aspects of each proposal.

1. Summary of Proposed Full Approval of the SIP

In one option of our co-proposal, we proposed to approve the following aspects of the State's June 4, 2015 SIP submittal:

- NO_X BART Alternative, including: NO_X emission reductions from Hunter Units 1, 2, and 3; Huntington Units 1 and 2; and Carbon Units 1 and 2; and sulfur dioxide (SO_2) and PM_{10} emission reductions from Carbon Units 1 and 2.
- BART determinations and emission limits for PM_{10} at Hunter Units 1 and 2 and Huntington Units 1 and 2.
- Monitoring, recordkeeping, and reporting requirements for units subject to the BART Alternative and the PM_{10} emission limits.

We also proposed to approve these elements of the State's October 20, 2015 SIP submittal:

- Enforceable commitments to revise SIP Section XX.D.3.c and State rule R307–150 by March 2018 to clarify emission inventory requirements for tracking compliance with the SO_2 milestone and properly accounting for the SO_2 emission reductions due to the closure of the Carbon plant.

2. Summary of Proposed Partial Approval and Partial Disapproval of the SIP and Proposal of a FIP

In the other option of our co-proposal, we proposed to approve these elements of the State's June 4, 2015 SIP submittal:

- BART determinations and emission limits for PM_{10} at Hunter Units 1 and 2 and Huntington Units 1 and 2.

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[1] Annual average NO_X emissions in tons per year for each of the four BART units for the period 2001–2003 were as follows: Hunter Unit 1 [6,380 tons/yr], Hunter Unit 2 [6,092 tons/yr], Huntington Unit 1 [5,944 tons/yr], Huntington Unit 2 [5,816 tons/yr].

[2] Refer to Tables 6 and 7 for visibility impacts.

[3] 81 FR 2004 (Jan. 14, 2016).

[4] For purposes of comparing the proposed BART Alternative to BART, Utah used most stringent NO_X control technology to represent BART, which is referred to as the BART Benchmark.

[5] 81 FR 2004, 2012–2020 (Jan. 14, 2016).

[6] Additionally, as discussed later in section I.B.3, at this time we not taking action on the State's October 20, 2015 enforceable commitment SIP submittal.

- Monitoring, recordkeeping, and reporting requirements for units subject to the PM_{10} emission limits.

We proposed to disapprove these aspects of the State's June 4, 2015 SIP submittal:

- NO_X BART Alternative, including NO_X emission reductions from Hunter Units 1, 2, and 3; Huntington Units 1 and 2; and Carbon Units 1 and 2; and SO_2 and PM_{10} emission reductions from Carbon Units 1 and 2.

We proposed to disapprove the State's October 20, 2015 SIP submittal.

We proposed promulgation of a FIP to address the deficiencies in the Utah regional haze SIPs that were identified in the proposed action. The proposed FIP included the following elements:

- NO_X BART determinations and emission limits for Hunter Units 1 and 2 and Huntington Units 1 and 2.
- Monitoring, recordkeeping, and reporting requirements for NO_X at Hunter Units 1 and 2, and Huntington Units 1 and 2.

B. Summary of the Basis for Our Final Decision

Based upon comments we received on our proposed action and our evaluation of both the State's submittals and those comments, in this final action we are partially approving and partially disapproving Utah's regional haze SIP submitted on June 4, 2015, and we are taking no action on Utah's regional haze SIP submitted on October 20, 2015. We are promulgating a FIP to address the deficiencies we have identified in the portions of the SIP that we are disapproving. Later we present a summary of the major points of our final decision regarding the Utah regional haze SIP submittal that we are acting on today in which we summarize which parts of the Utah regional haze SIP submittal we are approving and disapproving and which parts are cured by our FIP.

1. NO_X BART

As discussed in depth elsewhere in this document and in our separate Response to Comment (RTC) document, we considered the record before us and comments on both of our co-proposals, and have determined that the evidence does not clearly demonstrate that Utah's BART Alternative makes greater reasonable progress than BART; that is, we have determined that the State's Alternative is not clearly better than BART. Therefore, we are disapproving the BART Alternative contained in Utah's June 4, 2015 submittal and promulgating a FIP to satisfy the regional haze program's NO_X BART requirements.

In our co-proposal, to ensure our final decision was based on the best and most currently available data and information, we asked if interested parties had additional information in a number of areas, including: (1) Analysis related to the modeled visibility benefits of the BART Alternative compared to BART; and (2) other BART alternatives or BART control technology options related to what we proposed and that could be finalized as our FIP. We also asked if interested parties had additional information or comments on the proposed timeline of compliance.[7] We explained that any supplemental information we received could lead us to adopt final SIP and/or FIP regulations that differ somewhat from the co-proposals presented in our proposed rule regarding the BART Alternative, BART control technology option or emission limits, or impact other proposed regulatory provisions.[8] We did not receive any modeling analysis related to the benefits of the BART Alternative compared to BART or any suggestions for consideration of other BART alternatives or BART control technology options. However, we did receive extensive comments on our two possible evaluations of Utah's BART Alternative. As a result of these comments, we have revised some of the aspects of our evaluations of the State's BART Alternative metrics. Based on the revisions to our evaluations of the State's metrics, we have reassessed our co-proposed actions on the State's BART Alternative and determined that it does not demonstrate greater reasonable progress than BART. We provide our reassessment of the State's weight-of-evidence metrics in this section, and provide additional detail in our RTC document.

a. Regulatory Framework for BART Alternatives

To demonstrate that a BART alternative measure achieves greater reasonable progress than the BART requirements, EPA evaluates a SIP submittal to determine whether it demonstrates that the alternative will achieve greater reasonable progress toward natural visibility conditions than BART under 40 CFR 51.308(e)(3) or otherwise based on the *clear* weight of evidence.[9] The BART Alternative rule requires that the alternative program must "clearly" be better than BART, which we have explained is "when there is confidence that the difference in visibility impacts between BART and the alternative scenarios are expected *to be large enough*"[10] to ensure that that the alternative is, in fact, better. Therefore, as part of our evaluation of Utah's SIP we evaluated whether the differences in visibility impacts between BART and the State's BART Alternative are "large enough" to satisfy the *clear* weight-of-evidence requirement. The State of Utah opted to develop its SIP under the clear weight-of-evidence standard, and provided its analysis in the "Greater Reasonable Progress than BART" section of the SIP submittal.[11] As explained in our BART Alternative rule, the clear weight-of-evidence test follows these steps:[12]

(1) *Use information and data that can inform the decision.* Collect information that can be used to assess whether the proposed alternative measure will achieve greater reasonable progress than BART. The information is used to

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[7] 81 FR 2004, 2007, Jan. 14, 2016.

[8] *Id.*

[9] 40 CFR 51.308(e)(2)(i)(E).

[10] 71 FR 60622 ("In showing that an alternative program is better than BART and when there is confidence that the difference in visibility impacts between BART and the alternative scenarios are expected *to be large enough,* a weight of evidence comparison may be warranted in making the comparison." (emphasis added)).

[11] This section of the State's SIP submittal presents the BART Alternative rule regulatory requirements, including EPA's description that the clear weight of evidence standard uses information to inform a decision while recognizing the relative strengths and weaknesses of that information. The Utah SIP Section XX that was submitted to EPA, was adopted by the Air Quality Board on June 3, 2015, and included the proposed provisions to address the NO_X BART requirements. Footnote 4 in that Section of the SIP referenced the State's greater reasonable progress demonstration. The document referenced in the footnote was titled "Staff Review 2008 PM BART Determination and Recommended Alternative to BART for NO_X, Utah Division of Air Quality, May 13, 2015" ("Utah Staff Review Report" at 11).

[12] 71 FR 60612, 60622 (Oct. 13, 2006). As we explained in adding to our final RHR the "clear weight of the evidence" standard, " '[w]eight of evidence' demonstrations attempt to make use of all available information and data which can inform a decision while recognizing the relative strengths and weaknesses of that information in arriving at the soundest decision possible. Factors which can be used in a weight of evidence determination in this context may include, but not be limited to, future projected emissions levels under the program as compared to under BART, future projected visibility conditions under the two scenarios, the geographic distribution of sources likely to reduce or increase emissions under the program as compared to BART sources, monitoring data and emissions inventories, and sensitivity analyses of any models used. This array of information and other relevant data may be of sufficient quality to inform the comparison of visibility impacts between BART and the alternative program. In showing that an alternative program is better than BART and when there is confidence that the difference in visibility impacts between BART and the alternative scenarios are expected to be large enough, a weight of evidence comparison may be warranted in making the comparison. The EPA will carefully consider the evidence before us in evaluating any [state implementation plans] submitted by States employing such an approach." *Id.*

evaluate whether the *visibility* improvements at the Class I areas will be better under the alternative than under BART. Such information may include, but is not limited to, future projected emissions levels under the BART alternative as compared to under the BART benchmark; future projected visibility conditions under the two scenarios; the geographic distribution of sources likely to reduce or increase emissions under the program as compared to BART sources; monitoring data and emissions inventories; and sensitivity analyses of any models used.

(2) *Recognize the relative strengths and weaknesses of the information.* Evaluate the information and recognize the relative strengths and weaknesses of the metrics used. This process involves assigning weights to each piece of information that indicate the degree to which it supports a finding that the alternative program will achieve greater visibility benefits. Such a weighing system might find that: (i) The information *clearly* shows the alternative will achieve greater reasonable progress than BART; (ii) the information supports the alternative in some way, but not clearly; or (iii) the information does not support the alternative.

(3) *Carefully consider all the information to reach a conclusion.* Collectively consider the weights assigned to the individual pieces of information and consider the total weight of all the information to determine whether the proposed BART alternative will *clearly* provide for greater reasonable progress than BART at the impacted Class I areas.

Additionally, in this document, we occasionally point to the BART Guidelines for authority on the analysis of BART alternatives (*e.g.*, consideration of 98th percentile CALPUFF modeling).[13] We acknowledge that the BART Guidelines are not mandatory for the evaluation of BART alternatives and the Guidelines do not directly address this subject.[14] However, our rules at 40 CFR 51.309 and the preamble for the provisions governing alternatives to source-specific BART determinations[15] do not provide guidance on visibility modeling. We rely on the BART Guidelines here and in other actions involving BART alternatives because they provide a reasonable and consistent approach regarding visibility modeling, as well as other aspects of a BART alternative, conducted as part of a weight-of-evidence analysis.

b. Utah's "Greater Reasonable Progress Than BART" Metrics

The State collected and evaluated information "from a number of different metrics . . . to compare the two scenarios."[16] These nine metrics included: (1) Annual emissions of visibility-impairing pollutants; (2) improvement in the number of days with significant visibility impairment derived from CALPUFF modeling results; (3) 98th percentile modeling impact (deciview [dv]) results derived from CALPUFF modeling; (4) annual average impact (dv) derived from CALPUFF modeling results; (5) 90th percentile impact (dv) results derived from CALPUFF modeling; (6) timing of emissions reductions; (7) results from IMPROVE monitoring data; (8) energy and non-air quality benefits; and (9) costs. The State considered the information from these metrics and concluded that the weight-of-evidence shows that its alternative program will provide greater reasonable progress than BART.[17]

c. EPA's Evaluation of Utah's "Greater Reasonable Progress Than BART" Analysis

We evaluated the information for each of the nine metrics in the State's SIP submittal,[18] as well as additional information submitted by commenters. As part of this evaluation, we assessed the relevance and strength of each metric, that is, we assigned each metric a weight.[19] After determining if, and the extent to which, the information the State relied upon was "of sufficient quality to inform the comparison of visibility impacts between BART and the alternative program,"[20] we assessed the metrics collectively to determine whether the relevant evidence, considered as a whole, clearly demonstrated that the alternative program achieves greater visibility benefits.

Our initial review considered whether each of the nine metrics met the threshold regulatory requirement that information considered in a weight-of-evidence analysis be relevant to an assessment of visibility impacts. We find the State included two metrics, (1) energy and non-air quality impacts and (2) cost, that are inconsistent with the greater reasonable progress analysis in the RHR because the metrics do not evaluate *visibility* benefits at the nine Class I areas impacted by the State's sources. Therefore, as discussed in detail later in sections I.B.1.c.viii and I.B.1.c.ix, we did not give this information any weight in our evaluation of whether the State has demonstrated that its BART Alternative achieves greater reasonable progress than BART.

Additionally, the State included information on the aggregate annual emissions of all three visibility-impairing pollutants emitted by the sources. However, in this particular instance the aggregate emissions data do not provide information on the likely visibility impacts of the State's alternative program as compared to BART. Therefore, as discussed in detail later in section I.B.1.c.i, we found that this information was inconclusive and does not weigh either in favor of or against the BART Alternative.

Next, we evaluated how the State recognized the strengths and weakness of the remaining six metrics. The State placed each metric in one of two categories: The information from the metric supported the BART Alternative, or it did not. The State determined that five of the metrics supported the BART Alternative[21] and one metric, the 98th percentile CALPUFF modeling results, did not support the BART Alternative.[22] However, contrary to the requirement to *weigh* the evidence,[23] which Utah's SIP acknowledged is part of the weight-of-evidence standard,[24] the SIP submittal did not assess the relative strengths and weaknesses of the metrics; that is, it did not explain the *weight* that the State assigned to each of the metrics it found supported the BART Alternative. In evaluating the SIP submittal, we assessed the relative strengths and weakness of each of the State's metrics to determine whether it was reasonable for the State simply to categorize the metrics into the two categories (the metric supported the BART Alternative or did not support the Alternative). In addition to information in the submittal, we considered suggestions on the amount of "weight" that should be given to each of the metrics that were provided by commenters on our proposal, including the State.[25] As a result of our evaluation, we find that the State's assessment of the metrics was inadequate because it did not recognize the relative strengths and weaknesses of the metrics on an individual basis. We also find that a proper recognition of the relative strengths and weaknesses, including the consideration that some metrics are more meaningful than others, shows that the BART Alternative does not achieve greater reasonable progress than BART.

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[13] We also referred to the BART Guidelines as authority in our proposal.

[14] The BART Guidelines are mandatory in this action regarding both the State's determinations of the BART Benchmark pursuant to 40 CFR 51.308(e)(2)(i)(C) and EPA's BART determinations in the FIP pursuant to 40 CFR 51.308(e)(1)(ii)(B).

[15] 71 FR 60612, October 13, 2006.

[16] Utah Staff Review Report at 12.

[17] *Id.* at 27 and Utah's SIP, Section XX, Regional Haze (June 3, 2015) ("2015 SIP").

[18] Utah Staff Review Report at pp. 13–29.

[19] As discussed in this section, Utah did not assign a weight to each metric.

[20] 71 FR 60612, 60622.

[21] See Utah Staff Review Report at p. 27 (listing factors the State suggested to support the BART Alternative in the "Summary of Weight of Evidence" section).

[22] As discussed elsewhere, EPA disagrees with the State's evaluation of the 98th percentile metric.

[23] 40 CFR 51.308(e)(2)(i)(E).

[24] Utah Staff Review Report at 11 (the BART alternative regulatory provisions and EPA's description of the weight-of-evidence standard, including that a demonstration recognize the strengths and weaknesses of the information in arriving at the soundest decision possible, citing 71 FR 60612, 60622).

We evaluated each of the State's nine metrics and included: (1) An assessment of whether we agree as a factual matter with the State's conclusion; and (2) the weight we would give to each metric. Our evaluation below includes the two metrics that we find contain information that is not relevant, and the one to which we did not assign any weight.

i. Annual Emissions Comparison of All Visibility-Impairing Pollutants

The State's regional haze SIP submittal determined that the combined emissions of three key visibility-impairing pollutants will be lower under the BART Alternative scenario and that this supported the weight-of-evidence determination that the BART Alternative will provide greater reasonable progress than BART.[26][27] We proposed to find that, since Utah's BART Alternative provides greater emission reductions for two pollutants (SO_2 and PM_{10}), but that NOX emissions would be greater under the BART Alternative, it is not appropriate to combine all three pollutants in the annual emissions comparison test to support the BART Alternative. Therefore, we further proposed to find that the annual emissions comparison of all three pollutants does not show that the BART Alternative is better than the BART Benchmark.[28]

As a result of the comments received on our co-proposal, we have further assessed the State's evidence for this metric and while we have clarified our assessment, we have not changed our overall proposed findings. Although emissions of two visibility-impairing pollutants are less under the BART Alternative, emissions of one of the pollutants would be greater. Due to differences in visibility impacts and complex interactions between pollutants, it is not possible to discern the overall visibility impacts of the aggregate emission reductions in this case without modeling; as discussed elsewhere, we disagree with comments to the contrary. Therefore, while we consider that aggregate emission reductions is a relevant concept because it relates to visibility impacts, in this particular case we continue to find that it is not appropriate to combine all three pollutants in the annual emission comparison test. We thus find that this metric is inconclusive and does not weigh either in favor of or against the BART Alternative.

ii. Improvement in Number of Days With Significant Visibility Impairment

In its regional haze SIP submittal, Utah provided modeling results comparing the number of days with significant visibility *impairment* relative to natural visibility under the BART Alternative scenario to the number of days under the BART Benchmark. The State presented this information for two different thresholds of visibility impairment: 1.0 dv of impairment compared to natural visibility, and 0.5 dv of impairment. The State determined that the BART Alternative leads to an average of six fewer days per year with a visibility impact greater than 1.0 dv per year and 58 fewer days per year with a visibility impact greater than 0.5 dv at the nine Class I areas.[29] Utah also provided information in its submittal regarding the number of days with visibility *improvement* relative to baseline visibility (visibility conditions in 2001–2003) using a range of deciview thresholds (0.5 to 5.0 dv improvement compared to baseline visibility conditions).[30]

In EPA's review, we considered this metric in our evaluation of the State's weight-of-evidence analysis because the improvement in the number of days with significant visibility impairment relates to assessing the frequency and duration of visibility impacts. It is relevant to look at the results for the Class I areas individually because visibility impacts are location specific. The results for the average number of days with impacts over 1.0 dv show that seven of the nine Class I areas had the same result or were within one day of having the same result under both the BART Alternative and Benchmark. In the context of an entire year, a difference of one day is not particularly significant. Therefore, we find that the results from the average number of days with visibility impacts over the 1.0 dv threshold do not show the BART Alternative is better. We observe that the results for the average number of days with impacts over 0.5 dv show that the BART Alternative is better at five of nine Class I areas, and at four Class I areas the Alternative results in the same number of days with impacts greater than 0.5 dv as the Benchmark or is within two days of the same result (favoring the BART Alternative at each of the four where there is a two-day difference). Therefore, we find that the results from the 0.5 dv threshold show that the BART Alternative is marginally better.

iii. 98th Percentile Modeling Impact (dv)

In its regional haze SIP, the State determined that while the 98th percentile modeling impact showed greater reasonable progress under the BART Benchmark,[31] several considerations led to the State's conclusion that this metric does not give a complete picture of the visibility improvements that will be seen by visitors to Class I areas.[32] Therefore, the State's summary of the weight-of-evidence did not include the results from the 98th percentile modeling impact.[33] We assessed the State's evidence for this metric and proposed to find that on the whole, when using this method, the results from the BART Benchmark are slightly better on average across all years and nine Class I areas

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[25] The State's Comment letter suggested the "weight" for several of the metrics.

[26] 2015 SIP at 25, and Utah Staff Review Report at 27.

[27] EPA derived the following emissions reductions for the BART Alternative from the Utah Staff Review Report at 10, by subtracting the total annual emissions for the BART Alternative from the total annual emissions for the BART Benchmark for each of the visibility-pairing pollutants: SO_2 8,005 tpy, PM_{10} 573 tpy, and NO_X − 5,721 tpy (NO_X is negative because NO_X emissions increase under the BART Alternative). This information is also provided in Table 4 of our proposed rule. (81 FR 2004, 2016.)

[28] 81 FR 2004, 2029.

[29] EPA unintentionally created some confusion with regard to this metric in our proposed rule by expressing this information as the *total* number of days with visibility impairment greater than 1.0 and 0.5 dv in Tables 7 and 8, 81 FR 2004, 2017, based on modeling results presented in SIP TSD Ch. 6, Summary of Visibility Modeling. The State did not highlight these particular modeling results in this manner in its Utah Staff Review Report; rather, the State expressed this metric only as the average number of days per year over the three years modeled. We considered these modeling results, and as discussed in our RTC document, find that the results marginally support the Alternative.

[30] See Utah Staff Review Report, pp. 19–22, and Ch. 6, Summary of Visibility Modeling, and 2015 SIP at 25.

[31] Utah Staff Review Report at 24.

[32] *Id.* at 25.

[33] *See id.* at 27 ("Summary of Weight of Evidence" section does not include 98th percentile modeling impact results).

(0.14 dv average difference). Also, this metric shows greater visibility improvement at five of nine Class I areas for the BART Benchmark. We proposed to find, consistent with the State's evaluation, that this metric favors the BART Benchmark and does not show that the BART Alternative is better.[34]

As a result of the comments received on our co-proposal, we have further assessed the State's evidence for this metric and while we have clarified our assessment, we have not changed our overall proposed finding. We considered this metric in our evaluation of the State's weight-of-evidence analysis because the 98th percentile modeling results relate to assessing visibility impacts. We have considered all information, and consistent with the Agency's approach to assessing visibility benefits in both BART determinations and other determinations of "greater reasonable progress" using the CALPUFF model, have given most weight to the visibility impacts based on the 98th percentile air quality modeling results.[35]

iv. Annual Average Modeling Impact (dv)

The State's regional haze SIP submittal stated that the average deciview impact metric shows the benefit from the BART Alternative will be achieved day in and day out in the Class I areas.[36] This metric shows greater average visibility improvement at five of nine Class I areas for the BART Alternative.

We assessed the State's evidence for this metric and proposed to find that the BART Alternative is only marginally better than the BART Benchmark based on the difference in overall averages between the two scenarios of 0.009 dv and that it shows less or equal visibility improvement than BART at four of the nine Class I areas. Therefore, we proposed to find that the information from the annual average metric does not support a conclusion that the BART Alternative achieves greater reasonable progress than the BART Benchmark.[37]

As a result of the comments received on our co-proposal, we have further assessed the State's evidence for this metric and we have clarified our assessment and finding about the State's evaluation. We considered this metric in our evaluation of the State's weight-of-evidence analysis because the annual average modeling results relate to assessing visibility impacts. Importantly, we find that the annual average metric is less relevant than the 98th percentile because it does not provide information on visibility benefits on the days most impacted by the sources, which has been the focus of prior BART determinations[38] and other determinations of "greater reasonable progress" that relied on CALPUFF modeling.[39] Averaging the modeling results over an entire year dilutes the emission controls' (and BART Alternative emission reductions) potential visibility benefits and is inconsistent with the basis of the CALPUFF modeling approach used by the State. Additionally, the annual average visibility impact metric does not show greater visibility improvements than the Alternative at four of the nine affected Class I areas, and the average difference between BART and the Alternative across all nine of these areas is relatively small (0.009 dv). For these reasons, we find that the annual average impact metric in Utah's weight-of-evidence analysis only marginally supports the BART Alternative.

v. 90th Percentile Modeling Impact (dv)

The State's regional haze SIP submittal determined that the CALPUFF modeling results from the 90th percentile deciview impact show that the BART Alternative will provide greater improvement.[40] We assessed the State's evidence for this metric and proposed to find that although there was greater visibility improvement at seven of nine Class I areas for the BART Alternative, it was questionable if the BART Alternative was better based on the difference in the two scenarios of 0.006 dv. We therefore proposed to find that it is questionable whether the 90th percentile supports a conclusion that the BART Alternative achieves greater reasonable progress.[41]

As the result of the comments received on our co-proposal, we have further assessed the State's evidence for this metric and have clarified our assessment and finding. EPA has never used the CALPUFF 90th percentile results in other RH decisions, and we disapproved the use of the 90th percentile results for subject-to-BART modeling.[42] Here, though, we find it is appropriate to consider the CALPUFF 90th percentile results in evaluating the State's weight-of-evidence analysis because this metric provides some additional information about visibility benefits. However, we note that the 90th percentile metric excludes more than a month's worth of visibility data, which significantly dilutes the overall visibility results achieved from potential control options, and is therefore less relevant than the 98th percentile. Furthermore, while the 98th percentile day reflects visibility benefits on the days on which the sources have the largest impacts, the State has not indicated that the 90th percentile day has any particular significance other than to provide an additional metric to consider. We also acknowledge that the difference between BART and the BART Alternative using the 90th percentile is relatively small (0.006 dv). Additionally, we disagree with commenters that suggested the 90th percentile metric is similar to the 20% worst day metric; the 90th percentile relates to a single value, the 110th highest impact day across three years for the scenario considered (*i.e.*, BART Alternative or BART Benchmark), whereas the 20% worst days metric describes visibility impacts from all sources on the average of the 20% worst visibility days. Therefore, while we considered the results from the 90th percentile to evaluate the State's weight-of-evidence analysis, we placed a very small amount of weight on this metric, and therefore find that this metric only marginally supports the BART Alternative.

vi. Timing of the Emissions Reductions

The State's regional haze SIP submittal included statements in the greater reasonable progress than BART analysis that the NO_X reductions from Huntington Units 1 and 2 and Hunter

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[34] 81 FR 2004, 2030.

[35] *See* 81 FR 2004, 2021; 40 CFR part 51, appendix Y, section IV.D.5; 70 FR 39104, 39129 (July 6, 2005). *See, e.g.*, 78 FR 79344 (Dec. 30, 2012) (proposed rule, FIP for Tesoro Refining and Intalco Refinery BART Alternatives); 79 FR 33438 (June 11, 2014) (final rule, FIP for Tesoro Refining and Intalco Refinery BART Alternatives); 79 FR 56322, 56328 (Sept. 19, 2014) (proposed approval of Arizona Apache BART Alternative); 80 FR 19220 (Apr. 10, 2015) (final approval of Arizona Apache BART Alternative). We provide examples of use of the 98th modeling results for BART determinations in the RTC.

[36] Utah Staff Review Report at 23.

[37] 81 FR 2004, 2030.

[38] 40 CFR part 51, appendix Y, section IV.D.5; 70 FR 39104, 39129 (July 6, 2005). We provide examples of use of this information for BART determinations in the RTC.

[39] See, *e.g.*, 78 FR 79344, 79355 (Dec. 30, 2013) (proposed rule, FIP for Tesoro Refining and Intalco Refinery BART Alternatives in Washington), 79 FR 56322, 56328 (Sept. 19, 2014) (proposed approval of Arizona Apache BART Alternative).

[40] Utah Staff Review Report at 23–24, and 2015 SIP at 25.

[41] 81 FR 2004, 2030.

[42] In our North Dakota final action we explained that EPA addressed the appropriate interpretation of CALPUFF modeling results in the BART Guidelines within the context of subject-to-BART modeling and we rejected the use of the 90th percentile because it would be inconsistent with the Act. We explained that the use of the 90th percentile value would effectively allow visibility effects that are predicted to occur at the level of the threshold (or higher) on 36 or 37 days a year. 70 FR 39121.

Units 2 and 3 occurred earlier than was required by the rule, providing corresponding early and ongoing visibility improvement under the Alternative as compared to the BART Benchmark, citing to *WildEarth Guardians* v. *EPA*. 770 F.3d 919, 938 (10th Cir. 2014).[43]

The State further asserted that the timing of emission reductions provided support for the weight-of-evidence determination that the BART Alternative will provide greater reasonable progress than BART. We assessed the State's evidence for this metric and recognized that the reductions from the BART Alternative would occur before the BART Benchmark because the controls at the Hunter and Huntington facilities have been achieving significant NO_X reductions since the time of their installation between 2006 and 2014.[44]

As a result of the comments received on our co-proposal, we have further assessed the State's evidence for this metric. We considered the State's early emission reduction statement in our evaluation of the State's weight-of-evidence analysis because the reductions relate to assessing visibility impacts. We note that the State's weight-of-evidence analysis presents and considers only the early timing of emission reductions from the Hunter and Huntington units at which controls were installed before 2014.[45]

We find that the timing of emissions reductions metric, which considers the early reductions from Hunter Units 2 and 3 and Huntington Units 1 and 2, supports a finding that the BART Alternative is better than BART.

vii. Monitoring Data at the Class I Areas (IMPROVE Network)

The State's regional haze SIP submittal determined that the BART Alternative provides greater reductions of SO_2 [46] and that SO_2 is the most significant anthropogenic pollutant affecting Class I Areas that impacts visibility year-round, including throughout the high visitation seasons at the National Parks in spring, summer, and fall.[47] The State thus concluded, working from assumptions regarding sulfate and nitrate formation based on historical trend data,[48] that the BART Alternative will provide greater reasonable progress than BART.

We assessed the State's evidence for this metric and proposed to concur with one of the State's findings. We proposed to find that visibility benefits associated with NO_X reductions are much more likely to occur in the winter months because this is when aerosol thermodynamics favors nitrate formation, while SO_2 emissions reductions should provide visibility benefits in all seasons. We also proposed to find that, as concluded by the Grand Canyon Visibility Transport Commission (GCVTC), and supported by the IMPROVE monitoring data presented by Utah, anthropogenic visibility impairment on the Colorado Plateau is dominated by sulfates. Therefore, we proposed to concur with Utah's statement that sulfate is the largest contributor to visibility impairment at the affected Class I areas.

We proposed to disagree with the State's findings related to park visitation. While we explained that the BART Guidelines do mention visitation as something that can inform a control decision, EPA proposed to place little weight on the State's correlation of emissions reductions and park visitation because nothing in the CAA suggests that visitors during busy time periods are entitled to experience better visibility than visitors during off-peak periods.

As the result of the comments received on our co-proposal, we have further assessed the State's evidence for this metric and while we have clarified our assessment, our overall findings remain the same. We considered this metric in our evaluation of the State's weight-of-evidence analysis because the monitoring data relate to assessing visibility impacts. We conducted an analysis of 2013 and 2014 IMPROVE monitoring data for Canyonlands, the most impacted Class I area,[49] considering seasonal averages and the 20% best and worst days.[50] Our analysis confirms that sulfate is a large contributor to light extinction year round and that nitrate contributions are highest in the winter season. Nonetheless, overall nitrate extinction at the affected areas is significant, particularly on the 20% worst days. We have taken the strength of the modeling results for winter months into consideration; however, contrary to the State's and other's suggestions that visibility improvements during seasons of peak Class I area visitation should carry more weight, we evaluate the visibility impacts for an entire year, regardless of the season. Therefore, we decided to place little weight on this metric and find that the monitoring data analysis metric in Utah's weight-of-evidence analysis only marginally shows the BART Alternative is better than the BART Benchmark.

viii. Energy and Non-Air Quality Benefits

The State's regional haze SIP submittal indicated in its weight-of-evidence assessment that the BART Alternative would avoid the energy penalty associated with operating the SCR units, *i.e.*, the controls assumed under the BART Benchmark. The State also cited non-air quality benefits of its Alternative, including lower fly ash production and reduced water usage associated with the shutdown of Carbon. However, the State's "Summary of the Weight of Evidence," which presented a summary and short evaluation of each of the metrics, did not reference this assessment.[51]

We assessed the State's evidence for this metric and proposed to find that because the benefits do not have direct bearing on whether the BART Alternative achieves greater reasonable progress, it is not material to our action whether we agree or disagree with Utah's assessment that the Alternative would reduce energy and non-air quality impacts relative to BART.

As a result of the comments received on our co-proposal, we have further assessed the State's evidence for this metric; however, we have decided not to alter our proposed finding. The purpose of a weight-of-evidence analysis is to determine whether a BART Alternative would achieve greater reasonable progress, which is measured in terms of visibility improvement.[52] Thus, only metrics that are indicative of improvements in visibility are relevant in a weight-of-evidence analysis. Energy and non-air quality impacts do not provide relevant information on the relative visibility benefit of a BART Alternative as compared to BART. We, therefore, did not assign this metric any weight in our evaluation of the State's weight-of-evidence conclusion.

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[43] Utah Staff Review Report at 11, 27 ("The NO_X reductions at Huntington 1 and 2 and Hunter 2 and 3 occurred between 2006 and 2011, earlier than was required by the rule, providing an early and ongoing visibility improvement" and offering in footnote 14 that "[the] U.S. Circuit Court of Appeals for the 10th Circuit explicitly acknowledged that the consideration of early reductions was proper as part of a qualitative or clear weight of evidence approach to determining greater reasonable progress." (citing *WildEarth Guardians* v. *EPA*, 770 F.3d 919, 938 (10th Cir. 2014)). EPA agrees that it is appropriate to consider the timing of emission reductions for the Utah BART Alternative.

[44] 81 FR 2004, 2030.

[45] Utah Staff Review Report at 11.

[46] *Id.* at 27.

[47] *Id.* at 27.

[48] *Id.* at 12–19.

[49] Canyonlands was the most impacted Class I area in the State's BART Alternative modeling that assessed the visibility impacts from all three power plants (*i.e.*, Hunter, Huntington, and Carbon), as well as most impacted in EPA's modeling assessing the visibility impacts for the BART Benchmark for Hunter and Huntington.

[50] See spreadsheet entitled, EPA Analysis of 2013 and 2014 IMPROVE Monitoring Data for Canyonlands, in the docket. More detailed information regarding this analysis is available in section II.E of this document and in our RTC document.

[51] Utah Staff Review Report at 27.

[52] 40 CFR 51.308(d)(1), (e)(2)(i)(E).

ix. Cost

The State's regional haze SIP indicated in its weight-of-evidence assessment that, although the State had not officially determined the cost of BART, it is clear that the BART Alternative would have significant capital cost savings to PacifiCorp and its customers. The submittal noted that the Carbon Plant has already been closed and the cost to ratepayers of replacing the power generated by that facility have already occurred. However, the State's "Summary of the Weight of Evidence," which presented a summary and short evaluation of each of the metrics, did not reference the cost comparison.[53]

We assessed the State's evidence for this metric and proposed to find that because the described cost difference does not have a direct bearing on whether the BART Alternative achieves greater reasonable progress, it is not material to our action whether we agree or disagree with Utah's conclusion that the BART Alternative would have a lower cost impact to PacifiCorp than the BART Benchmark (*i.e.,* costs provided by PacifiCorp in its BART analyses of August 5, 2014, SIP TSD Chapter 2).

As a result of the comments received on our co-proposal, we have further assessed the State's evidence for this metric; however, we have decided not to alter our proposed finding. The purpose of a weight-of-evidence analysis is to determine whether a BART Alternative would achieve greater reasonable progress, which is measured in terms of visibility improvement.[54] The difference in the capital costs between BART and the BART Alternative does not provide information relevant to the scenarios' relative visibility benefits.[55] We therefore did not assign this metric any weight in our evaluation of the State's weight-of-evidence conclusion.

x. EPA's Evaluation of the State's Conclusions

The State's regional haze SIP submittal suggested that eight of the nine metrics considered by Utah support the BART Alternative, finding that one metric, the 98th percentile CALPUFF modeling metric did not support its BART Alternative. As explained earlier in this section, evidence in the SIP and from commenters demonstrates that four of these metrics have documented weaknesses and only marginally support the BART Alternative: Improvement in the number of days with significant visibility impairment predicted by modeling (analyzed using different thresholds); the annual average visibility impacts predicted by modeling; monitoring data trends collected at the Class I areas; and the 90th percentile impacts predicted by modeling. Additionally, while the timing of emission reductions metric does favor the State's BART Alternative, the emission reductions at issue are only a portion of the overall emission reductions claimed under the Alternative. The timing of these emission reductions does not alter our conclusion that, on balance, the Alternative has not been shown to result in greater visibility benefits than would BART. Finally, we did not assign any weight to three metrics in our evaluation of the State's weight-of-evidence analysis because we determined that the metrics for energy and non-air quality and cost considerations are not related to visibility and have no bearing on whether the BART Alternative achieves greater reasonable progress than the BART Benchmark, and that information from the annual emissions comparison of all visibility-impairing pollutants metric was inconclusive.

When we weighed the State's metrics (excluding the energy and non-air quality and cost metrics) that evaluate visibility collectively, considering the strengths and weaknesses of each metric and the magnitude of the differences in visibility benefit between BART and the Alternative, we find that it was not reasonable for the State to determine that the clear weight of the evidence favors the BART Alternative for the following reasons. We find that the State's characterization of the 98th percentile modeling results, the one metric that did not support its BART Alternative, was contrary to EPA's established interpretation of and reliance on that metric. The 98th percentile CALPUFF modeling metric takes into account peak visibility impacts and carries the most weight. The 98th percentile visibility impact is a key metric recommended by the BART Guidelines and EPA has relied on this metric in evaluating prior regional haze actions that have included BART alternatives.[56] Furthermore, two factors which marginally support the BART Alternative (annual average modeled impact and 90th percentile modeled impact) are given little weight because they are considered to be less relevant metrics and show very small differences between the BART Alternative and the BART Benchmark, while another factor which marginally supports the BART Alternative (results from IMPROVE monitoring data) is also given little weight because of the need to consider visibility impacts during all times of the year, not just during peak visitation periods. Another factor which marginally supports the BART Alternative (improvement in number of days with significant visibility impairment) is given little weight because even though the BART Alternative is favored using a 0.5 dv threshold, the 1.0 dv threshold does not show that the BART Alternative is better. In addition, although a portion of the emission reductions under the Alternative were achieved prior to 2014, this does not diminish our fundamental finding that the quantity of reductions available under the Alternative would not result in greater visibility improvements than the emission reductions under BART. Therefore, the visibility metrics that favor the BART Alternative neither individually nor collectively clearly demonstrate that the BART Alternative will achieve greater reasonable progress at the nine Class I areas when weighed against visibility benefits predicted by the 98th percentile modeling results under BART.

In summary, we have relied on the standards contained in the RHR and the authority that Congress granted us to review SIPs to determine whether the State's SIP submittal complies with the minimum statutory and regulatory requirements. In determining SIP adequacy, we must exercise our judgment and expertise regarding complex technical issues, and it is entirely appropriate that we do so. Courts have recognized this necessity and deferred to our exercise of discretion when reviewing SIPs.[57] We thus review a state's SIP submittal with the understanding that the state's discretion in developing an alternative measure "is subject to the condition that it must be reasonably exercised and that its decision is supported by adequate documents of its analysis." [58] In the present circumstance—as discussed in more detail in the proposed action and this final action—EPA was not able to find that the weight-of-evidence analysis satisfied the relevant regulatory requirements. Specifically, we find:

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[53] Utah Staff Review Report at 27.

[54] 40 CFR 51.308(d)(1), (e)(2)(i)(E).

[55] We also note that, consistent with our statements in the BART Guidelines, the capital cost of controls would not be a relevant consideration because it does not take into account the degree of visibility improvement associated with those controls. 40 CFR part 51, appendix Y, section IV.D.4.g. Therefore, even if we did consider cost as relevant in a weight-of-evidence analysis, which we do not, the capital cost of controls would not be the appropriate metric.

[56] *See, e.g.,* 78 FR 79344 (Dec. 30, 2012) (proposed rule, FIP for Tesoro Refining and Intalco Refinery BART Alternatives); 79 FR 33438 (June 11, 2014) (final rule, FIP for Tesoro Refining and Intalco Refinery BART Alternatives); 79 FR 56322, 56328 (Sept. 19, 2014) (proposed approval of Arizona Apache BART Alternative); 80 FR 19220 (Apr. 10, 2015) (final approval of Arizona Apache BART Alternative).

(1) The State's assessment of the metrics it found to support its BART Alternative was inadequate because it did not evaluate the relative strengths and weaknesses of the visibility metrics on an individual basis;

(2) The State did not consider the 98th percentile CALPUFF modeling metric, which did not support its BART Alternative, in a manner consistent with EPA's established interpretation of and reliance on that metric;

(3) The State's assessment of the metric that considered aggregate annual emissions of visibility-impairing pollutants was contrary to EPA's established interpretation of and reliance on that metric;

(4) The State's assessment relied on two metrics that are not consistent with the "greater reasonable progress" analysis because they are not related to visibility (energy and non-air quality and cost considerations);

(5) The State did not satisfy the requirement that it assess the collective weight of its evidence in a reasonable and adequately supported manner; and

(6) The SIP submittal lacked an explanation of why the information from all the metrics demonstrated that the difference in visibility impacts between BART and the Alternative was large enough to "clearly" demonstrate that the BART Alternative would achieve greater reasonable progress than BART.[59]

Based on this evaluation, we find that, on balance, the evidence does not show that the Alternative clearly achieves greater visibility benefits than BART. Thus, the State has not satisfied the regulatory requirement in 40 CFR 51.308(e)(2) that a state's submittal of a BART alternative include a "determination . . . based on the clear weight of evidence that the . . . alternative measure achieve greater reasonable progress than would be achieved through the installation and operation of BART at the covered sources." Therefore, we are disapproving the State's $\mathrm{NO_X}$ BART Alternative contained in its June 4, 2015 SIP submittal, including the $\mathrm{NO_X}$ emission limits for Hunter Units 1, 2, and 3; and the $\mathrm{NO_X}$ emission limits for Huntington Units 1 and 2; and the requirements for permanent closure of Carbon Units 1 and 2.[60]

d. Remaining BART Alternative Criteria

The RHR establishes a number of additional regulatory criteria to be included in any demonstration that an alternative will provide for greater reasonable progress than BART. These criteria are set out at 40 CFR 51.308(e)(2)(i)(A)–(D) and (e)(2)(iii)–(v). In both co-proposals, we proposed to find that Utah's SIP submittal addressing the BART Alternative met these requirements.[61] We received adverse and supportive comments on our proposed finding that the State had met these remaining requirements. We respond to these comments in our RTC document.

Having carefully considered the comments received, we have concluded that the State's SIP submittal generally met most of these requirements, as explained in our RTC document. As a result, our partial disapproval of the State's SIP submittal is based on our assessment that Utah failed to demonstrate based on the weight of evidence that the BART Alternative would provide for greater reasonable progress and not on any deficiencies in the state's demonstration that it had met the additional regulatory criteria in 40 CFR 51.308(e)(2).

e. Monitoring, Recordkeeping and Reporting for Utah's BART Alternative

Section IV.B.3 of Utah's June 2015 regional haze SIP included enforceable measures and monitoring, recordkeeping and reporting requirements for the Utah BART Alternative and the State's PM_{10} BART determinations. In our co-proposal we proposed to disapprove (in other words, to not make federally enforceable as part of the SIP) the monitoring, recordkeeping and reporting requirements located in SIP Sections IX.H.22 associated with the BART Alternative. This includes SIP Section IX.H.22, subsections a.ii, a.iii, b.ii, and c.i.[62]

While we did not receive any comments on this element of Utah's regional haze SIP submittal in our co-proposal, the monitoring, recordkeeping, and reporting provisions in the submittal are linked directly to the emission limitations under the Alternative, which we are disapproving.[63] Our partial disapproval of the State's SIP submittal is based on our assessment that Utah failed to demonstrate based on the weight of evidence that the BART Alternative would provide for greater reasonable progress and not on any deficiencies in the State's demonstration that it had met the monitoring, recordkeeping, and reporting requirements under the RHR.

f. Basis for Our $\mathrm{NO_X}$ BART Determinations and FIP

Based upon comments we received on our proposed FIP, we revised our analysis of the cost of installing and operating $\mathrm{NO_X}$ BART controls at the four subject-to-BART EGUs. In particular, and as discussed at length in our RTC document, we revised the costs in response to comments from PacifiCorp that we incorrectly re-designed the SCR reactors. Having carefully considered the comments received, we concluded it was unnecessary to revise our analysis of visibility improvement or the other statutory BART factors. Our proposed action contains a full description of the five step BART analysis, the five BART factors, and our proposed BART determination. Because we have revised our cost analysis, we provide updated tables containing the results of the cost analyses, including the summary tables that also show the visibility improvements associated with the controls under consideration (which we did not revise). Following these tables, we provide our final BART determination. Because the Hunter and Huntington BART units are similar, our reasoning for the final BART determination applies to all four units. Table 1 shows the NO_X BART control technologies, associated cost, emission reductions, and the BART emission limitation for each source that is subject to the FIP. The costs in Table 1 reflect EPA's revised cost analysis. Please note that the cost-effectiveness values for SCR with low-NO_X burners and separated overfire air (SCR + LNB/SOFA) were computed using an assumed emission rate of 0.05 lb/MMBtu on an annual basis, but for compliance purposes the NO_X emission limit for each unit is 0.07 lb/MMBtu, 30-day rolling average.

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[57] See, *e.g.*, Connecticut Fund for the *Env't., Inc.* v. *EPA*, 696 F.2d 169 (2d Cir. 1982); *Michigan Dep't. of Envtl. Quality* v. *Browner*, 230 F.3d 181 (6th Cir. 2000); *Montana Sulphur & Chem. Co.* v. *EPA*, 2012 U.S. App. LEXIS 1056 (9th Cir. Jan. 19, 2012).

[58] 71 FR 60612, 60621 (Oct. 13, 2006).

[59] The State's assessment of the overall weight of evidence states only that "[t]he weight of evidence shows that the alternative will provide greater reasonable progress than BART." Utah Staff Review Report at 27.

[60] We are disapproving SIP Sections IX.H.21, subsection (c), IX.H.22, subsections:.a.iii–iii., b.ii. and c. We are also disapproving SIP Section XX,D subsections: 6.a. (the provisions in the "Regional Haze Rule BART Requirements" that cover the $\mathrm{NO_X}$ alternative measure); 6.c. ("BART for $\mathrm{NO_X}$. " including footnote 4 that references the State's Analysis in a separate document); 6.d. (the provisions in the "BART Summary" that cover $\mathrm{NO_X}$ and SO_2 emissions, including the references to use of approval orders and permitted limits to establish the emission limits, the statement that "the four EGUs also met the presumptive emission rates for both $\mathrm{NO_X}$ and SO_2 established in Appendix Y independently of the alternative programs", and references in Table 5 to "Permitted" (and the $\mathrm{NO_X}$ and SO_2 limits in that column), "Hunter 3", all provisions in the "Presumptive BART Rates" column $\mathrm{NO_X}$ and SO_2 emissions); 6.e. (the provisions in "Schedule for Installation of Controls" as the dates refer to emissions for sources that are in the proposed BART Alternative; and the discussion immediately following Table 6 that presents information about the emission limits also appearing in State-issued permits). Additional discussion appears in our RTC document.

[61] 81 FR at 2021, 2025–26, 2027–28, 2032

[62] As explained later, our co-proposal proposed to approve or conditionally approve the remainder of the monitoring, recordkeeping and reporting requirements associated with Utah's PM_{10} BART determinations.

[63] However, we note that we are proposing conditional approval of the following regulations in Section IX.H.21(e), as discussed in section I.B.2.

TABLE 1—EMISSION LIMITS, COSTS, AND COST EFFECTIVENESS FOR LNBS/SOFA WITH SCR FOR THE SOURCES SUBJECT TO THE FIP

Source	Technology *	NO_X Emission limit—lb/MMBtu (30-day rolling average)	Total capital cost ($)	Total annualized cost ($)	Average cost-effectiveness ($/ton)
Hunter Unit 1	SCR + LNB/SOFA	0.07	$130.6M	$14.8M	$2,697
Hunter Unit 2	SCR + LNB/SOFA	0.07	128.5M	14.5M	2,774
Huntington Unit 1	SCR + LNB/SOFA	0.07	128.3M	14.6M	2,871
Huntington Unit 2	SCR + LNB/SOFA	0.07	130.0M	14.7M	2,928

* The technology listed is the technology evaluated as BART, but sources can choose to use another technology or combination of technologies to meet established limits.

Tables 2 and 3 provide summaries of EPA's NO_X BART analysis of all feasible control options for Hunter Units 1 and 2, including the costs of compliance and visibility impacts. Please refer to our discussion in section I.B.1.f in regard to how we selected BART from among these control options.

TABLE 2—SUMMARY OF EPA'S HUNTER UNIT 1 NO_X BART IMPACTS ANALYSIS

Control option	Annual emission rate (lb/MMBtu)	Emission reduction (tpy)	Total annual costs (million$)	Average cost effectiveness ($/ton)	Incremental cost effectiveness ($/ton)	Visibility impacts *		
						Improvement (dv)	Days > 0.5 dv	Days > 1.0 dv
LNB with SOFA	0.21	3,042	$1.2M	$382		0.846	330 (29)	218 (22)
LNB with SOFA and SNCR	0.16	3,735	3.8M	1,016	3,796	1.041	322 (37)	202 (38)
LNB with SOFA and SCR	0.05	5,500	14.8M	2,697	6,255 (compared to LNB with SOFA and SNCR) 5,561 (compared to LNB with SOFA).	1.545	311 (48)	188 (52)

* At the most impacted Class I area, Canyonlands National Park. The improvement in days over 0.5 and 1.0 dv provided by the control option relative to the baseline is presented in parentheses. See Table H.9. Air Quality Modeling Protocol: Utah Regional Haze Federal Implementation Plan, US EPA Region 8 (Nov. 2015); Docket Id. EPA–R08–OAR–2015–0463–0012.

TABLE 3—SUMMARY OF EPA'S HUNTER UNIT 2 NO_X BART IMPACTS ANALYSIS

Control option	Annual emission rate (lb/MMBtu)	Emission reduction (tpy)	Total annual costs (million$)	Average cost effectiveness ($/ton)	Incremental cost effectiveness ($/ton)	Visibility impacts *		
						Improvement (dv)	Days > 0.5 dv	Days > 1.0 dv
LNB with SOFA	0.20	2,902	$0.9M	$298		0.658	336 (23)	221 (19)
LNB with SOFA and SNCR	0.16	3,562	3.5M	968	3,913	0.822	331 (28)	218 (22)
LNB with SOFA and SCR	0.05	5,230	14.5M	2,774	6,632 (compared to LNB with SOFA and SNCR) 5,861 (compared to LNB with SOFA).	1.250	317 (42)	198 (42)

* At the most impacted Class I area, Canyonlands National Park. The improvement in days over 0.5 and 1.0 dv provided by the control option relative to the baseline is presented in parentheses. See Table H.10. Air Quality Modeling Protocol: Utah Regional Haze Federal Implementation Plan, US EPA Region 8 (Nov. 2015); Docket Id. EPA–R08–OAR–2015–0463–0012.

Tables 4 and 5 provide summaries of EPA's NO_X BART analysis of all feasible control options for Huntington Units 1 and 2, including the costs of compliance and visibility impacts.

TABLE 4—SUMMARY OF EPA'S HUNTINGTON UNIT 1 NO_X BART IMPACTS ANALYSIS

Control option	Annual emission rate (lb/MMBtu)	Emission reduction (tpy)	Total annual costs (million$)	Average cost effectiveness ($/ton)	Incremental cost effectiveness ($/ton)	Visibility impacts*		
						Improvement (dv)	Days > 0.5 dv	Days > 1.0 dv
LNB with SOFA	0.22	2,440	$0.8M	$332		0.851	249 (28)	153 (22)
LNB with SOFA and SNCR	0.17	3,185	3.5M	1098	3,609	1.113	244 (33)	143 (32)
LNB with SOFA and SCR	0.05	5,092	14.6M	2,871	5,830 (compared to LNB with SOFA and SNCR) 5,206 (compared to LNB with SOFA).	1.881	210 (67)	117 (58)

* At the most impacted Class I area, Canyonlands National Park. The improvement in days over 0.5 and 1.0 dv provided by the control option relative to the baseline is presented in parentheses. See Table H.11. Air Quality Modeling Protocol: Utah Regional Haze Federal Implementation Plan, US EPA Region 8 (Nov. 2015); Docket Id. EPA–R08–OAR–2015–0463–0012.

TABLE 5—SUMMARY OF EPA'S HUNTINGTON UNIT 2 NO_X BART IMPACTS ANALYSIS

Control option	Annual emission rate (lb/MMBtu)	Emission reduction (tpy)	Total annual costs (million$)	Average cost effectiveness ($/ton)	Incremental cost effectiveness ($/ton)	Visibility impacts*		
						Improvement (dv)	Days > 0.5 dv	Days > 1.0 dv
LNB with SOFA	0.21	2,576	$0.9M	$365		0.776	254 (23)	153 (22)
LNB with SOFA and SNCR	0.17	3,264	3.5M	1,075	3,730	1.016	244 (33)	149 (26)
LNB with SOFA and SCR	0.05	5,023	14.7M	2,928	6,368 (compared to LNB with SOFA and SNCR) 5,626 (compared to LNB with SOFA).	1.657	220 (57)	126 (49)

* At the most impacted Class I area, Canyonlands National Park. The improvement in days over 0.5 and 1.0 dv provided by the control option relative to the baseline is presented in parentheses. See Table H.12. Air Quality Modeling Protocol: Utah Regional Haze Federal Implementation Plan, US EPA Region 8 (Nov. 2015); Docket Id. EPA–R08–OAR–2015–0463–0012.

In our final BART determinations, we have taken into consideration all five of the statutory factors required by the CAA: Costs of compliance, energy and non-air quality environmental impacts of compliance, any existing pollution control technology in use at the source, remaining useful life of the source, and degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology.

We received some comments on our proposed consideration of remaining useful life and energy and non-air quality environmental impacts. However, we have not changed our evaluation from the proposal of the energy and non-air quality environmental impacts of compliance and the remaining useful lives of the sources. We find that the remaining useful life of the Hunter and Huntington units of at least twenty years is considerable and does not require us to revise our amortization period for the costs of controls. We also find that the energy and non-air quality environmental impacts of the various control options do not significantly favor one option over another. Please see the proposal action and our RTC document for details.

We also received comments on our proposed consideration of existing pollution control technology in use at the source, in this case LNB/SOFA at all four BART units. For reasons explained later in the preamble and in our RTC document, we continue to use a baseline period for emissions (2001–2003) that predates the installation of LNB/SOFA at the four BART units. We have considered the existing LNB/SOFA in several other ways. First, we considered them in selecting the control options to analyze for BART. Second, we considered them in determining the impacts of the control options, both by taking the LNB/SOFA into account in determining the proper NO_X rates for the post-combustion control options (selective non-catalytic reduction (SNCR) and SCR), and in computing the incremental cost-effectiveness values in the tables earlier. We also consider the existing LNB/SOFA in our discussion of incremental visibility benefits later. As explained later in the preamble and in our RTC document, this is a reasonable approach and consistent with other actions.

We now discuss the remaining factors, the costs of compliance and the degree of visibility improvement, and how we are weighing them in determining BART. At this point in time, EPA and the states have made a number of BART determinations for large coal-fired EGUs. EPA is taking into account the BART decisions made in other states to help frame our assessment of the cost and visibility benefits of control options in this action.[64] Specifically, we have compared the average cost-effectiveness, incremental cost-effectiveness, visibility improvement, and incremental visibility improvement for the selected BART controls, SCR + LNB/SOFA, with BART determinations for coal-fired EGUs where the EPA and states have based those determinations on the same or similar metrics.

The most comparable determination is in EPA's final action on Wyoming's regional haze SIP, in which EPA promulgated a FIP for three units at Laramie River Station and determined NO_X BART to be SCR + LNB/SOFA for the three units.[65] On a per-unit basis, the visibility improvement at the most impacted Class I area from this control option ranged from 0.52 to 0.57 dv, and across all three units the sum of the improvement was 1.62 dv.[66] Thus, applying this control option to all three units of Laramie River Station was estimated to have a visibility benefit about the same as applying the same control option to just one of the Hunter and Huntington BART units (the visibility benefits in today's action at the most impacted Class I area range from 1.25 dv at Hunter Unit 2 to 1.881 dv at Huntington Unit 1). The visibility benefits of SCR + LNB/SOFA at Hunter or Huntington as a whole (2.948 dv for Hunter, 3.848 dv for Huntington) are significantly greater than at Laramie River Station.

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[64] As discussed in our proposal action, in the context of reasonable progress determinations, a comparison with another reasonable progress determination has been upheld by the Ninth Circuit Court of Appeals as a rational explanation for that determination. Nat'l Parks Conserv. Ass'n v. U.S. EPA, 788 F.3d 1134, 1148–49 (9th Cir. 2014).

[65] 79 FR 5032, 5047 (Jan. 30, 2014).

[66] As explained in our proposal, the BART Guidelines require consideration of the visibility improvement from the use of BART controls applied to the collection of emissions units that make up the BART source. Although this requires consideration of the visibility improvement from BART applied to the subject-to-BART source as a whole, states (and EPA) may also include the visibility benefits on a per unit basis as well in their evaluation of the BART factors. In this action we have considered both the per-unit visibility benefits as well as the source-wide visibility benefits. The source-wide visibility benefits of our selected BART control, SCR + LNB/SOFA, at all nine impacted Class I areas are presented and discussed later.

The average cost-effectiveness for SCR + LNB/SOFA at Laramie River Station ranged from $4,375/ton to $4,461/ton, considerably higher than the corresponding values of $2,697/ton to $2,928/ton for the Hunter and Huntington BART units. The incremental cost-effectiveness for SCR + LNB/SOFA at Laramie River Station as compared to SNCR + LNB/SOFA ranged from $5,449 to $5,871/ton, which is generally in line with the corresponding values for the Hunter and Huntington BART units, $5,830/ton to $6,632/ton. Finally, the incremental visibility improvement for SCR + LNB/SOFA at the most impacted Class I area as compared to SNCR + LNB/SOFA for Laramie River Station was significant (0.25 dv to 0.29 dv), but is even more so for the Hunter and Huntington BART units (0.428 dv at Hunter Unit 2 to 0.748 dv at Huntington Unit 1). Thus, the selection of SCR + LNB/SOFA at the Hunter and Huntington BART units is very much in line with the selection of SCR + LNB/SOFA at Laramie River Station. This is particularly true given that Laramie River Station impacts four Class I areas, while the Hunter and Huntington BART units impact nine Class I areas.

In the same Wyoming action, our BART determinations for Dave Johnston Units 3 and 4 also provide a useful comparison. At Unit 3, we selected SCR + LNB/OFA as BART based on an assumed 20-year remaining useful life. Under that assumption, the average cost-effectiveness and incremental cost-effectiveness (as compared to SNCR + LNB/OFA) were $2,635/ton and $7,583/ton, respectively. We found these costs reasonable in light of a 0.51 dv improvement and a 0.12 dv incremental improvement at the most impacted Class I area. The average cost-effectiveness of SCR + LNB/SOFA at the Hunter and Huntington BART units, $2,697/ton to $2,928/ton, is comparable, while the incremental cost-effectiveness of SCR + LNB/SOFA at the Hunter and Huntington BART units, $5,830/ton to $6,830/ton, is less than at Dave Johnston Unit 3. On the other hand, the visibility benefit and incremental visibility benefit of SCR + LNB/SOFA at the Hunter and Huntington BART units is considerably higher than that at Dave Johnston Unit 3, and the Hunter and Huntington BART units impact nine Class I areas as compared to five for Dave Johnston Unit 3. Thus, the selection of SCR + LNB/SOFA for the Hunter and Huntington BART units is very much in line with our BART determination for Dave Johnston Unit 3 (assuming a remaining useful life of 20 years).

In the Wyoming action, at the request of PacifiCorp we also analyzed an alternative compliance scenario for Dave Johnston Unit 3 that assumed a shutdown in 2027 and correspondingly a 9-year remaining useful life. As explained in the BART Guidelines, for BART units with a relatively short remaining useful life—in other words, less than the time period used for amortizing costs, which in this case was 20 years—the shorter time period can be used to amortize costs instead. Effectively, this increases the cost-effectiveness values; in the case of Dave Johnston Unit 3, the average and incremental cost-effectiveness of SCR + LNB/OFA increased to $3,742/ton and $11,781/ton, respectively. Considering these values against the visibility benefits, we found that the incremental cost-effectiveness of SCR + LNB/OFA in this instance was not reasonable. Of course, for the Hunter and Huntington BART units the incremental cost-effectiveness is much lower than this scenario and in line with the previous scenario assuming a 20-year remaining useful life, for which we selected SCR + LNB/OFA as BART. Similarly, for Dave Johnston Unit 4, as for the 9-year remaining useful life scenario for Unit 3, we rejected SCR + LNB/OFA due to a high incremental cost-effectiveness of $13,312. This is again consistent with our determination here, given the much lower incremental cost-effectiveness numbers for SCR + LNB/SOFA at the Hunter and Huntington BART units.

There are other BART determinations in which SCR has been selected as BART (either alone or in conjunction with LNB and SOFA) based on similar metrics, although those determinations may not have explicitly discussed incremental cost-effectiveness and incremental visibility benefits on a per-unit basis. First, the State of Colorado selected, and the EPA approved, SCR as NO_X BART for Public Service Company's Hayden Station, Units 1 and 2.[67] Hayden Units 1 and 2 were equipped with first generation LNB and over-fire air (OFA) installed in 1999 as the result of a consent decree to address other CAA requirements.[68] In its BART determination, Colorado considered these existing controls as given and included them in the baseline emissions, which is consistent with our approach here: Colorado included the Hayden combustion controls in the baseline because they were not installed for a proposed BART determination but for other CAA purposes. In contrast, we do *not* include the combustion controls at Hunter and Huntington because they *were* installed pursuant to a proposed BART determination.[69]

Colorado analyzed as feasible controls upgraded LNB, SNCR, and SCR. Based on an average cost-effectiveness of $3,385/ton and $4,064/ton, incremental cost-effectiveness (as compared with SNCR + the existing LNB/OFA) of $5,326/ton and $7,331/ton, and visibility improvement of 1.12 dv and 0.85 dv at the most impacted Class I area, respectively, Colorado selected SCR (added to the existing LNB/OFA) as BART for Units 1 and 2. The average cost-effectiveness of SCR + LNB/SOFA at the Hunter and Huntington BART units, $2,697/ton to $2,928/ton, compares favorably with the average cost-effectiveness of SCR at the Hayden units, and the incremental cost-effectiveness of SCR + LNB/SOFA at the Hunter and Huntington BART units, $5,830/ton to $6,632/ton, is generally in line with the incremental cost-effectiveness of SCR at the Hayden units. The visibility improvement from SCR + LNB/SOFA at the most impacted Class I area for the Hunter and Huntington BART units, from 1.25 dv to 1.881 dv, compares favorably with the Hayden units. While Colorado appears to have not considered the incremental visibility benefits, these are also favorable for our selection of SCR + LNB/SOFA: 0.428 dv to 0.768 at the Hunter and Huntington units, as compared to 0.37 dv and 0.43 dv at Hayden Units 1 and 2, respectively. We also note that Hayden Station impacts eleven Class I areas, slightly more than Hunter and Huntington; however for six of those areas the impacts from Hayden Station are less than the impacts from Hunter and Huntington at the least impacted Class I area, Zion National Park.[70]

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[67] 77 FR 18069 (Mar. 26, 2012) (proposal); 77 FR 76871 (Dec. 31, 2012) (final).

[68] Colorado Department of Health and Environment, Air Pollution Control Division, Technical Review Document, Renewal/Modification of Operating Permit 96OPRO132, Public Service Company—Hayden Station, Colorado, at 2 (2007–2008).

[69] We respond later in this action and in our RTC document about comments that this comparison should not be used because the baseline for Hayden included the existing controls.

Another comparable determination can be found in EPA's FIP for Arizona Public Service's Cholla Power Plant, Units 2, 3, and 4, in which EPA determined that NO$_X$ BART was SCR for all three units.[71] Similar to Colorado's determination for Hayden, EPA included the existing controls, LNB and OFA, in the baseline for the three units.[72] EPA estimated average cost-effectiveness values for SCR (as added to the existing LNB/OFA) of $3,114/ton, $3,472/ton, and $3,395/ton; and incremental cost-effectiveness values (as compared to SNCR + LNB/OFA) of $3,257/ton, $3,811/ton, and $3,661/ton, respectively, for Units 2, 3, and 4. EPA's modeling showed a source-wide visibility improvement for SCR of 1.34 dv at the most impacted Class I area. In comparison, the source-wide visibility improvements at the most impacted Class I area for Hunter and Huntington from SCR + LNB/SOFA are much larger: 2.948 dv and 3.848 dv, respectively. While the average cost-effectiveness values at Cholla are somewhat higher than those for the Hunter and Huntington BART units, the incremental cost-effectiveness of SCR at the Hunter and Huntington BART units is considerably higher, at $5,830/ton to $6,632/ton. Despite that disparity in incremental cost-effectiveness, this comparison still supports selection of SCR + LNB/SOFA for the Hunter and Huntington BART units, given the much greater magnitude of the visibility benefits and the fact that our other comparisons show the incremental cost-effectiveness of SCR + LNB/SOFA is still reasonable. Finally, Cholla Power Plant does impact somewhat more Class I areas, thirteen as opposed to nine for Hunter and Huntington; however, were we to sum the baseline impacts of Hunter and Huntington, they would be greater than those for Cholla.

Based on these comparisons to Laramie River Station, Hayden Station, Dave Johnston Units 3 and 4, and Cholla Power Plant Units 2, 3, and 4, the selection of LNB and SOFA with SCR as BART for the Hunter and Huntington BART units is fully justified.[73] For these four units, LNB and SOFA with SCR is very cost-effective, at $2,697/ton to $2,928/ton on an average basis (counting the costs and emission reductions from the combination of the three control technology elements), and at $5,830/ton to $6,632/ton on an incremental basis compared to LNB with SOFA and SNCR. Compared to LNB with SOFA, the incremental cost effectiveness of LNB and SOFA with SCR ranges from $5,206/ton to $5,861/ton, which is in line with the incremental cost effectiveness that supported the selection of LNB with SOFA and SCR for Laramie River Station. For the Hunter and Huntington BART units, LNB and SOFA with SCR provides substantial visibility benefits at several Class I areas that are similar in magnitude to those from Laramie River Station. For example, the visibility improvement from that control option installed on a single unit is 1.342 dv at Arches National Park, 1.545 dv at Canyonlands National Park, and 1.113 at Capitol Reef National Park. These comparisons show that costs are justified in light of the substantial visibility benefits, both total and incremental. In addition, for each unit, SCR + LNB/SOFA provides a significant improvement in the number of days over 0.5 dv as compared to the baseline (ranging from 42 days improvement at Hunter Unit 2 to 67 days improvement at Huntington Unit 1).

As mentioned earlier, the BART Guidelines require consideration of the visibility improvement from the use of BART controls applied to the collection of emissions units that make up the BART source. Tables 6 and 7 summarize the source-wide visibility improvements from the installation of SCR + LNB/SOFA at both BART units at Hunter and both BART units at Huntington, as well as the visibility improvements from the installation of SCR + LNB/SOFA at the other impacted Class I areas.

TABLE 6—SUMMARY OF SOURCE-WIDE VISIBILITY IMPACTS AND IMPROVEMENTS FOR HUNTER

Class I area	Baseline visibility impacts			BART (SCR + LNB/SOFA) Impacts (Improvements over baseline shown in parentheses)		
	Impacts (dv)	Days > 0.5 dv	Days > 1.0 dv	Impacts (dv)	Days > 0.5 dv	Days > 1.0 dv
Arches National Park (NP)	4.601	293	170	1.981 (2.62)	158 (135)	71 (99)
Black Canyon NP	1.097	68	22	0.481 (0.616)	14 (54)	1 (21)
Bryce Canyon NP	1.833	42	22	0.811 (1.022)	20 (22)	6 (16)
Canyonlands NP	5.356	359	240	2.408 (2.948)	223 (136)	111 (129)
Capitol Reef NP	4.606	175	118	2.171 (2.435)	114 (61)	55 (63)
Flat Tops Wilderness	1.281	77	31	0.537 (0.744)	22 (55)	1 (30)
Grand Canyon NP	1.891	49	32	0.730 (1.161)	25 (24)	9 (23)
Mesa Verde NP	1.327	82	32	0.514 (0.813)	21 (61)	4 (28)
Zion NP	0.963	29	14	0.369 (0.594)	10 (19)	4 (10)

Note: The baseline impacts are the combined impacts from all three units at Hunter, while the BART source is comprised of only units 1 and 2. EPA's evaluation of visibility under BART relies only on the visibility benefits associated with controls on the two BART units.

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[70] See BART CALPUFF Class I Federal Area Individual Source Attribution Visibility Impairment Modeling Analysis for Public Service Company of Colorado Hayden Station Units 1 and 2, Colorado Department of Public Health, at 48 (Nov. 1, 2005).

[71] 77 FR 42834 (July 20, 2012) (proposal); 77 FR 72512, 72514–15 (Dec. 5, 2012) (final).

[72] In response to a comment about the use of this baseline, EPA explained that the three Cholla units had installed LNB/OFA and switched to a new source of coal with a much higher potential for NO$_X$ emissions. Thus, the LNB/OFA had not been installed pursuant to a proposed state BART determination; instead they appear to have been installed to accommodate the use of the new coal. This is again distinguishable from the situation for Hunter and Huntington.

[73] As explained later and in our RTC document, we reject the comparisons to BART determinations in Montana, Florida, and Nebraska.

TABLE 7—SUMMARY OF SOURCE-WIDE VISIBILITY IMPACTS AND IMPROVEMENTS FOR HUNTINGTON

Class I area	Baseline visibility impacts			BART (SCR + LNB/SOFA) impacts (improvements shown in parentheses)		
	Impacts (dv)	Days > 0.5 dv	Days > 1.0 dv	Impacts (dv)	Days > 0.5 dv	Days > 1.0 dv
Arches NP	3.887	237	146	0.848 (3.039)	67 (170)	18 (128)
Black Canyon NP	0.773	45	16	0.196 (0.577)	1 (44)	0 (16)
Bryce Canyon NP	1.221	36	19	0.326 (0.895)	4 (32)	0 (19)
Canyonlands NP	5.130	277	175	1.282 (3.848)	89 (188)	31 (144)
Capitol Reef NP	3.389	131	91	0.986 (2.403)	42 (89)	9 (82)
Flat Tops Wilderness	0.926	64	17	0.216 (0.710)	2 (62)	0 (17)
Grand Canyon NP	1.107	40	19	0.190 (0.806)	4 (36)	0 (19)
Mesa Verde NP	1.115	63	22	0.261 (0.854)	0 (63)	0 (22)
Zion NP	0.820	21	11	0.211 (0.609)	3 (18)	0 (11)

As can be seen from these tables, the baseline visibility impacts in dv at all nine Class I areas are large: Even at the least impacted Class I area, Zion National Park, Hunter and Huntington are each above the 0.5 dv threshold for contributing to visibility impairment. For Hunter, at the three most impacted Class I national park areas, Arches, Canyonlands and Capitol Reef, the baseline visibility impacts range from 4.601 dv to 5.356 dv. At these three Class I areas, the number of days with impacts over 0.5 dv and 1.0 dv range from 175 to 359, and from 118 to 240, respectively. The visibility benefits of BART (SCR + LNB/SOFA) at the three Class I areas are correspondingly large, ranging from 2.435 dv to 2.948 dv. The improvement in the number of days over 0.5 dv and 1.0 dv at these three Class I areas are large as well, ranging from an improvement of 61 to 136 days in the number of days over 0.5 dv and 63 to 129 days in the number of days over 1.0 dv. Even at the least impacted Class I area, Zion National Park, the visibility benefits of BART are significant, 0.594 dv, and 19 and 10 days in the number of days over 0.5 dv and 1.0 dv, respectively. Consideration of these source-wide visibility benefits confirms that SCR + LNB/SOFA at Hunter is fully justified in light of its reasonable costs.

For Huntington, at the three most impacted Class I national park areas, Arches, Canyonlands and Capitol Reef, the baseline visibility impacts range from 3.389 dv to 5.130 dv. At these three Class I areas, the number of days with impacts over 0.5 dv and 1.0 dv range from 131 to 271, and from 91 to 175, respectively. The visibility benefits of BART (SCR + LNB/SOFA) at the three Class I areas are correspondingly large, ranging from 2.063 dv to 3.538 dv. The improvement in the number of days with impacts from Huntington over 0.5 dv and 1.0 dv at these three Class I areas are similar to those of Hunter. Huntington has 89 fewer days with impacts over 0.5 dv at Capitol Reef, 170 fewer days with such impacts at Archers, and 188 fewer days at Canyonlands. The number of days Huntington has impacts over 1.0 dv at these areas falls by 82 to 144 days. Even at the least impacted Class I area, Zion National Park, the visibility benefits of BART are significant. BART is projected to result in a 0.609 dv improvement at Zion the number of days with impacts over 0.5 dv and 1.0 dv fall by 18 and 11 days, respectively. Consideration of these source-wide visibility benefits confirms that SCR + LNB/SOFA at Huntington, as at Hunter, is fully justified in light of its reasonable costs.

Accordingly, for the Hunter and Huntington BART units, we find that BART for NO_X is SCR + LNB/SOFA, represented by an emission limitation of 0.07 lb/MMBtu (30-day rolling average). The BART emission limitation of 0.07 lb/MMBtu allows for a sufficient margin of compliance for a 30-day rolling average limit that would apply at all times, including startup, shutdown, and malfunction.[74] We are also finalizing our proposed monitoring, recordkeeping, and reporting requirements in our regulatory text for 40 CFR 52.2336; these requirements will ensure that the BART emission limitation is enforceable.

Under 40 CFR 51.308(e)(1)(iv), "each source subject to BART [is] required to install and operate BART as expeditiously as practicable, but in no event later than five years after approval of the implementation plan revision." In light of the considerable effort involved to retrofit SCR, we determine that five years is as expeditiously as practicable. Therefore, the compliance deadline for the BART requirements will be five years from the date our final FIP becomes effective.

2. PM_{10} BART

We are finalizing our proposed approval of Utah's PM_{10} BART determinations for Hunter Units 1 and 2 and Huntington Units 1 and 2. We have determined that Utah's PM_{10} BART determinations, emission limitations, and associated monitoring, recordkeeping and reporting for Hunter Units 1 and 2 and Huntington Units 1 and 2 meet the requirements of 40 CFR 51.309(d)(4)(vii) and the linked BART requirements in 40 CFR 51.308(e)(1).[75] We are approving SIP Section IX, Part H.21 subsections a through d and f (related to applicability, definitions, recordkeeping, and stack testing), and conditionally approving Subsection e (emission limitations shall apply at all times). We are approving SIP Section IX, Part H.22 subsections a.i and b.i. We considered and rejected comments on the validity of the State's BART analyses for PM_{10} and the State's emission limitation of 0.015 lb/MMBtu on a 30-day rolling basis for the Hunter and Huntington BART units. For PM_{10} reporting, we are finalizing our proposed conditional approval of this element in accordance with CAA section 110(k)(4), based on Utah's commitment to submit specific measures to address the reporting requirement.[76] Utah's letter commits to adopt and submit rule language that would require sources to report any deviation from the requirements of the regional haze SIP provisions, which would include the PM_{10} emission limitations. The specific language is detailed in Utah's commitment letter. We did not receive any adverse comments on our conditional approval of the recordkeeping requirements for the PM_{10} emission limitations.

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[74] Emission limits such as BART are required to be met on a continuous basis. *See* 70 FR 39104, 39172 (July 6, 2005) (stating that emissions limits including BART are to be met on a "continuous basis" in the BART Guidelines, section V); 42 U.S.C. 7602(k) (noting that emission limits are to be on "a continuous basis").

[75] As discussed elsewhere, while we are approving the PM_{10} emission limits in SIP Section IX, Part H.21, we are not approving into the SIP the "approval orders" (*i.e.*, State-issued permits) that are referenced in SIP Section XX.D.6.d at 25 and 29).

[76] Letter from Department of Environmental Quality, State of Utah to EPA, DAQP–120–15 (Dec. 10, 2015).

Pursuant to CAA section 110(k)(4), the State has one year from the date of this action to adopt and submit the necessary SIP revisions for SIP Section IX.H.21.e. If the State does not meet its commitment within the one year period, the conditional approval is treated as a disapproval. EPA finds that the necessary SIP revisions meet EPA's criteria for conditional approvals,[77] as the revisions appear to involve a limited amount of technical work, are anticipated to be non-controversial, and can reasonably be accomplished within the length of time for the State's adoption process.

3. Enforceable Commitment SIP

We are taking no action on Utah's enforceable commitment SIP, submitted on October 20, 2015. In its enforceable commitment SIP submittal, the State resolved to address double counting certain emissions reductions from the Carbon power plant closure under both the Utah BART Alternative and the SO_2 backstop trading program under 40 CFR 51.309. As we explained in our proposal, we interpret our authority to enable us to approve enforceable commitment SIPs under section 110(a)(2)(A) of the Act and other applicable sections as relevant (for our NO_X BART action, this is section 169A). However, since we are not approving the State's NO_X BART Alternative SIP submittal, which included emissions reductions from the Carbon power plant, there is no need for the elements of the enforceable commitment SIP. Additionally, because we are not taking action on the enforceable commitment SIP package submitted on October 20, 2015 we are not responding to comments on that SIP in this action.

II. Summary and Analysis of Major Issues Raised by Commenters

We received both written and oral comments at the public hearings we held in Salt Lake City. We also received comments by the Internet and mail. The full text of comments received from these commenters is included in the publicly posted docket associated with this action at *www.regulations.gov.* Our RTC document, which is also included in the docket associated with this action, provides detailed responses to all significant comments received. In total, we received approximately 4,900 pages of significant comments. Later we provide a summary of the more significant comments received and a summary of our responses to them. Our RTC document is organized similarly to the structure presented in this section (*e.g.,* Cost of Controls, BART Alternative CALPUFF Modeling, etc.). Therefore, if additional information is desired concerning how we addressed a particular comment, the reader should refer to the appropriate section in our RTC document.

PacifiCorp, conservation organizations (HEAL Utah, National Parks Conservation Association, and Sierra Club) and the National Parks Service (NPS) submitted detailed comments that include new cost and visibility modeling information.[78] Several government, tourism and industry organizations also submitted comments. Many general comments were made at the public hearing. We received approximately 400 comments through email and the *www.regulations.gov* Web site. We also received approximately 70,000 mass mailer comments from private citizens.

A. General Comments

Comment: Several commenters expressed concern over the accommodations provided at the public hearing. Several commented on the large number of attendees, and how this made it difficult for them to make their comments as well as hear those who were speaking. Commenters noted that many attendees were intimidated by the size of the hearing and by some of the other attendees, and suggested that many attendees left the hearing without commenting on the issues. There was concern that these departures may have led to an imbalance in opinions presented. Some commenters noted that some of the attendees at the hearing were not being cordial with the others and were unkind to those who expressed different opinions. Several commenters made requests for additional hearings, suggesting that additional hearings be located closer to the affected Class I areas and at locations that could accommodate a larger number of attendees.

Response: Several commenters expressed their dissatisfaction with EPA's public hearing arrangements. As required by section 307(d)(5) of the CAA the EPA provided an opportunity for the public to submit written comments and voice concerns at the public hearing. In arranging the logistics for the public hearing, EPA's intent was to provide an opportunity for all members of the public to voice their opinions about the proposed rulemaking. The Salt Lake City library was chosen as the public hearing site because: (1) The library had reasonable accommodations to hold approximately 100 attendees; (2) the library was centrally located, and would be convenient for many members of the public to access; and (3) the library did not require a fee. The size of the venue was consistent with other hearings the EPA has conducted across the country.[79] Based on these considerations, the EPA had no reason to believe the venue could not accommodate the anticipated level of public participation or that it would not fulfill the purposes of and the Act's requirements for the hearing.

While the number of individuals attending the public hearing exceeded what we anticipated, we made adjustments throughout the day to accommodate the large numbers. For example, the library staff worked with us and set up broadcast speakers in the hallway so that those in the hallway could hear what was said during the hearing. The EPA could not allow the meeting room used for the public hearing to exceed its capacity limit in order to comply with the library's policies to comply with the fire code occupancy requirements. In response to the unkind statements made by some participants, the Hearing Officer reminded the crowd that the purpose of the meeting was to allow people to testify comfortably without being intimidated, and that people causing distractions would be asked to leave. In fact, some attendees who were causing distractions were asked to leave. Additionally, even though the turnout was larger than expected, EPA scheduled the opportunity for the public to speak based on their arrival time (with those arriving first, first allowed to speak); and the EPA accommodated all the potential speakers at the end of the scheduled hearing time, by extending the hearing until everyone who was present at that time and wanted to speak had done so. As a result the hearing was extended by approximately 20 minutes.

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[77] *See* Memorandum from John Calcagni to EPA Regional Directors. "Processing of State Implementation Plan (SIP) Submittals" (July 1992), available at *http://www3.epa.gov/ttn/oarpg/t1/memoranda/siproc.pdf.*

[78] On May 19, 2015, PacifiCorp submitted late comments. These comments are included in the docket for this action and we address them in our RTC document.

[79] Examples include: (1) The public hearing on FIP proposal on May 1, 2012 at the Lewis and Clark Library in Helena, MT; (2) the public hearing on FIP proposal on July 27, 2013 at the Laramie County Library in Cheyenne, WY; and (3) the public hearing on FIP proposal on October 13–14, 2011 at the North Dakota Department of Health Training Center in Bismarck, ND.

The EPA determined that additional hearings were unnecessary, because the written comment period continued for approximately seven weeks after the public hearing, allowing for additional comments to be submitted. As explained in the proposed rule,[80] in addition to the public hearing, the EPA accepted written comments provided those comments were received on or before March 14, 2016. Therefore, while some of the members of the public may have left before they had an opportunity to speak at the hearing, they still had the opportunity to submit their comments either online or via mail to EPA for approximately seven weeks after the public hearing, as demonstrated in 81 FR 2004. The EPA gives just as much consideration to comments we receive in writing as we do to those we receive at public hearings.

B. EPA Authority and State Discretion

Comment: The State of Utah commented that EPA should approve its BART Alternative because it meets all of the current requirements of the CAA and the RHR found at 40 CFR 51.300 through 51.309. EPA is obligated to approve a SIP that meets all of the applicable requirements of the CAA. See 42 U.S.C. 7410(k)(3) ("In the case of any submittal on which the Administrator is required to act under paragraph (2), the Administrator shall approve such submittal as a whole if it meets all of the applicable requirements of this chapter."). The Section 308 regulation grants states full discretion as to whether to adopt the BART Alternative. In the current proposed rule, EPA also acknowledges a state's discretion in approving alternative measures: Finally, in . . . responding to concerns regarding "impermissibly vague" language in § 51.308(e)(3) that would allow a State to "approve alternative measure that are less protective than BART," we explained that "[t]he State's discretion in this area is subject to the condition that it must be reasonably exercised and that its decision be supported by adequate documentation of its analyses." 81 FR 2004, 2012 (quoting 71 FR 60612, 60621 (Oct. 13, 2006)). Therefore, the alternative measure is within the state's discretion, as long as it is adequately supported.

Response: We agree that states have discretion to adopt BART alternatives; however, as the commenter explains, the state's discretion is subject to a number of requirements, including that it be reasonably exercised and adequately supported and that the state's Alternative clearly provides greater reasonable progress than BART. The CAA requires that states submit SIPs that contain such measures as may be necessary to make reasonable progress toward achieving natural visibility conditions, including the BART requirements. As EPA explained when promulgating the regional haze regulations, "[t]he overarching requirement of the visibility protection provisions of section 169A is to make reasonable progress toward the national goal of eliminating visibility impairment. If greater reasonable progress can be made through an approach that does not require source specific application of BART, EPA believes that approach would comport with this statutory goal." [81] States have the opportunity to adopt alternative measures in lieu of BART where the agency *reasonably concludes* that more reasonable progress will thereby be attained toward the national visibility goal.[82] We explained these requirements in our co-proposal as follows: "[a]s described in our 2006 revisions to the RHR, concerning BART alternatives, '[t]he State's discretion in this area is subject to the condition that it must be reasonably exercised and that its decisions be supported by adequate documentation of its analyses.' "[83]

While states have discretion to decide whether to adopt a BART alternative in a SIP, such discretion does not extend to the authority to adopt SIPs that will not ensure reasonable progress toward the national visibility goal of preventing any future and remedying of any existing visibility impairment in Class I areas. Such an interpretation is also inconsistent with the legislative history, which stresses the importance of the "national goal" [84] of clear air quality in Class I areas and "preventing impairment of visibility," noting that "the millions of Americans who travel thousands of miles each year to visit Yosemite or the Grand Canyon or the North Cascades will find little enjoyment if . . . upon reaching the Grand Canyon it is difficult if not impossible to see across the great chasm." [85]

Thus, we do not agree that Congress assigned states full discretion in developing SIPs, because it is not clear how EPA's limited role under such a scenario would assure attainment of the national goal or imposition of the [better than] BART requirements where a state's BART alternative demonstration does not demonstrate that the alternative achieves greater reasonable progress. In view of the statutory requirements, it is logical that EPA would evaluate the reasonableness of the State's BART Alternative analysis in light of the purpose of the regional haze program.

As detailed in the sections in our co-proposal and based on our evaluation and findings as detailed in Section I.B.1 of this document and in our RTC document, we determined that, on balance, the evidence does not show that the Alternative clearly achieves greater visibility benefits than BART. Because the State's BART Alternative is not approvable, we are obligated to disapprove it, develop BART analyses, and then arrive at our own BART determinations for the four EGUs that are subject-to-BART.

Furthermore, this is a SIP review action, and we believe that EPA is not only authorized, but required to exercise independent technical judgment in evaluating the adequacy of the State's regional haze SIP, including its BART Alternative analyses, just as EPA must exercise such judgment in evaluating other SIPs. In evaluating other SIPs, EPA is constantly exercising judgment about SIP adequacy, not just to meet and maintain the NAAQS, but also to meet other requirements that do not have a numeric value. In this case, Congress did not establish a specific numeric value by which to measure visibility improvement; instead, it established a reasonable progress standard and required that EPA assure that such progress be achieved via implementation, *inter alia,* of the Act's BART requirement. Here, we are exercising judgment within the parameters laid out in the CAA and our regulations.

Our evaluation of the State's BART Alternative is presented in section I.B.1 and in our RTC document.

Comment: The State commented that EPA mistakenly imposes additional inapplicable requirements in its evaluation of Utah's regional haze SIP. Greater reasonable progress under Section 308(e)(2) can be demonstrated using either one of two methods: (1) Greater emission reductions than under BART (Section 308(e)(3)); or (2) the weight-of-evidence test, consisting of a number of requirements that the state weighs to conclude which option achieves greater reasonable progress (section 308(e)(2)). *See* 40 CFR 51.308(e)(2) and (3). The state has discretion to choose one method over the other. *See WildEarth Guardians* v. *E.P.A.,* 770 F.3d 919, 935–37 (10th Cir.

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[80] 81 FR 2004 (Jan. 14, 2016).

[81] 64 FR 35714, 35739 (July 1, 1999).

[82] *Id.* (emphasis added).

[83] 81 FR 2004, 2006 (Jan. 6, 2016) (citing 71 FR 60612, 60621 (Oct. 13, 2006)).

[84] 42 U.S.C. 7491(a)(1).

[85] H.R. Rep. No. 95–294, at 137 (1977).

2014). The Tenth Circuit characterized the former approach as "quantitative" and the latter as "qualitative," ultimately ruling that EPA can properly rely on qualitative factors in applying the "weight-of-evidence test." *See id.* at 934–35 (EPA's choice of qualitative standard was "permissible under the EPA's interpretation of its regulations.").

Utah submitted its BART Alternative under Section 308(e)(2), purposefully electing to make its determination that the alternative program achieves greater reasonable progress under the "weight-of-evidence" test. EPA analyzed Utah's BART Alternative in both co-proposals under the section 308(e)(3) "greater emissions reductions test" in addition to the "weight-of-evidence" analysis. See 81 FR 2004, 2021, 2028. EPA proposed that Utah's BART Alternative does not result in greater emission reductions because "the total NO$_X$ emissions are greater under the BART Alternative than the BART Benchmark," even though "in the aggregate there are fewer SO$_2$ and PM$_{10}$ emissions for the BART Alternative . . . ." *Id.* at 2028. EPA erroneously imposed Section 308(e)(3) requirements on Utah's BART Alternative in addition to the Section 308(e)(2) weight-of-evidence test. EPA must withdraw its analysis of Utah's BART Alternative under the greater emissions reductions test because, as Utah clearly explained, the State never intended its data to satisfy this test.

Response: We agree in part and disagree in part with this comment. In developing a BART Alternative SIP, we agree that a state has the discretion to choose between the "greater emission reduction" test (section 308(e)(3)) and the "weight-of-evidence" test (section 308(e)(2)). Utah's comments clarify that they elected the weight-of-evidence test, and so we clarify and modify our evaluation of the State's SIP submittal. We therefore clarify that we are not disapproving the SIP under the elements of the section 308(e)(3) test as we had proposed.[86]

The State's submittal, however, asserted that the BART Alternative is better than BART based in part on the metric that compared annual emissions of the three visibility impairing pollutants in the aggregate. There is no requirement in section 308(e)(2) for the State to compare annual emissions of visibility pollutants in the aggregate. Rather, as we explained in our proposal, we have addressed this issue under section 308(e)(3); our interpretation under that provision also applies under section 308(e)(2). Specifically, if under section 308(e)(2) a state compares annual emissions of visibility in the aggregate to determine whether a BART alternative "results in greater emission reductions," we examine whether each of the visibility causing pollutants is less under the alternative. For the reasons explained in our proposal and in section I.B.1.c.i of this document, we have not approved a BART alternative where one or more of the specific pollutants under the BART alternative is greater than it would be under the BART benchmark.[87]

Therefore, as we did in our proposal, it is reasonable to apply our interpretation of the section 308(e)(3) "greater emission reductions" element under section 308(e)(2) as well, because the same concerns regarding the relationship between reductions of multiple pollutants and visibility improvements are also relevant in the weight-of-evidence context.

Comment: PacifiCorp asserted that EPA is not empowered under the CAA to require compliance with both the SIP proposal and the FIP proposal. As a practical matter, that is precisely what EPA proposes to do to the extent it approves the FIP proposal. This is because PacifiCorp already has implemented the SIP proposal as required by Utah law. If EPA were to select the FIP proposal, it would do so knowing[88] that PacifiCorp would be required to implement both the SIP proposal and the FIP proposal. Nothing in CAA or regional haze rules allows EPA to require such a result when the proposed action itself states that EPA "intends to finalize only one proposal." See 81 FR 2004, 2006.

For all of the reasons stated earlier, EPA should approve the Utah SIP as stated in the SIP proposal, and should reject the FIP proposal. What EPA cannot do, and indeed is not empowered under the CAA to require, is compliance with both the SIP proposal and the FIP proposal.

Response: We disagree with this comment. As explained elsewhere, the CAA requires that states submit SIPs that contain such measures as may be necessary to make reasonable progress toward achieving natural visibility conditions, including the BART requirements. EPA is acting under its authority pursuant to the CAA in disapproving portions of the SIP submittal and promulgating the FIP. We have the duty to ensure that regional haze SIP submittals meet the requirements of the Act and the RHR.[89] While states have the opportunity to adopt alternative measures in lieu of

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[86] 81 FR 2004, 2028 ("Therefore, we propose to disapprove Section XX.D.6.c. of the Utah SIP under the test in 40 CFR 51.308(e)(3).").

[87] EPA's interpretation of the requirement under 40 CFR 51.308(e)(3) that the alternative measure "results in greater emission reductions" has been that the emission reduction comparisons are pollutant specific. We have applied this interpretation in evaluating BART alternatives and we have not looked at a total emissions profile that combines emissions of multiple pollutants to determine whether a BART benchmark or a BART alternative is "better," except where every visibility impairing pollutant is reduced by a greater amount under the BART alternative. See 79 FR 9318, 9335 (Feb. 18, 2014) (proposed approval of Arizona BART Alternative for Sundt Unit 4); 79 FR 52420 (Sept. 3, 2014) (final approval of Arizona BART Alternative for Sundt Unit 4); 77 FR 18052, 18073–75 (Mar. 26, 2012) (proposed approval of Colorado BART Alternative, no modeling required where the 40 CFR 51.308(e)(3) test was met); 77 FR 76871 (Dec. 31, 2012) (final approval of Colorado BART Alternative). EPA has not relied on a total emissions profile that combines emissions of multiple pollutants together to determine that either BART or a BART alternative is "better," because visibility modeling is the most appropriate method to assess the overall improvements in visibility impacts from control scenarios where reductions of multiple pollutants are considered, except where every visibility impairing pollutant is reduced by a greater amount under the alternative. As we have explained, "[e]ach of the five pollutants which cause or contribute to visibility impairment has a different impact on light extinction for a given particle mass, making it therefore extremely difficult to judge the equivalence of interpollutant trades in a manner that would be technically credible, yet convenient to implement in the timeframe needed for transactions to be efficient. This analysis is further complicated by the fact that the visibility impact that each pollutant can have varies with humidity, so that control of different pollutants can have markedly different effects on visibility in different geographic areas and at different times of the year." See 64 FR 35714, 35743(July 1, 1999). As other Agency actions on BART alternatives have explained, modeling assesses "both pollutants' chemical aerosol formation mechanisms and impacts on visibility," (see 78 FR 79344, 79355; Dec. 30, 2013) which allows evaluation of the "relative visibility impacts from the atmospheric formation of visibility impairing aerosols of sulfate and nitrate." See 79 FR 33438, 33440 (June 11, 2014).

[88] EPA is well aware that the Utah SIP, as it has been implemented over time, became binding state law in regard to the Utah BART Units and ultimately the other units covered by the BART Alternative. This makes it particularly egregious that, even though EPA knew that PacifiCorp was required to expend hundreds of millions of dollars to fully implement the BART Alternative under state law, EPA said nothing about its intention to issue a competing co-proposal until after PacifiCorp had completed all of the emission reductions required under the Utah SIP. *See* Letter from Carl Daly to Bryce Bird, Re. EPA Region 8 Comments on Utah's February 2015 Draft Regional Haze SIP Revision, at 1 (May 1, 2015) (commenting on the then-proposed Utah SIP including the BART Alternative). This secretive approach by EPA also caught the Utah Division of Air Quality off guard as explained in their oral comments during the January 26, 2016 hearing: "Throughout the SIP development process, we worked as regulatory partners, closely and extensively with EPA staff to ensure that Utah's Alternative to BART SIP revision met all the requirements of the Clean Air Act and was approvable by EPA. The EPA should approve the option that Utah developed while in close consultation with EPA and not the option that Utah was not even aware was being prepared or under consideration until it was proposed in the **Federal Register**."

[89] *See* CAA sections 169A and 110(k)(3).

BART, their discretion in this area is subject to the condition that it must be reasonably exercised and that their decisions be supported by adequate documentation of its analyses.

Therefore, we do not agree that we are prohibited from identifying deficiencies in the Utah SIP submittal after the State rulemaking process is complete, and the commenter cites nothing in the Act to the contrary. While a state may adopt regulations that are effective as a matter of state law before EPA goes through its rulemaking process to evaluate the proposed SIP elements, those state rules are not federally enforceable because any SIP submittal "shall not be treated as meeting the requirements of this chapter until the Administrator approves the entire plan revision as complying with the applicable requirements." 42 U.S.C. 7410(k)(3). The State's and EPA's roles in this process were understood in PacifiCorp statements. For example, in response to a question provided during rebuttal testimony that asked whether the regional haze rules are final, the Company explained that the 2011 Utah and Wyoming SIP submittals "are final insofar as state action is considered" and recognized that "these submittals have not yet been approved by the Environmental Protection Agency."[90]

The commenter suggests that measures in Utah's SIP submittal became "binding state law in regard to the Utah BART Units" and "the other units covered by the BART Alternative" prior to EPA's final action. The commenter merely suggests there are state law provisions but does not provide citations to any state law specific provisions.[91] It appears, however, that the commenter may be referring to measures established pursuant to the State's permit process. If this is, indeed, what the commenter is referring to, both the CAA and our regulations require that emission limits be established pursuant to a BART or BART alternative determination, and be contained in an EPA-approved SIP.[92] The fact that Utah chose to use its permit process to establish emission limits for its BART sources before EPA completed its review of the State's SIP submittal has no bearing on EPA's authority and obligation to conduct this review and to approve or, if necessary, disapprove the State's submittal.

Finally, EPA's comment letter on the State's proposed SIP clearly explained that "we will only come to a final conclusion regarding the regional haze program for Utah when we take action on the program through our own public notice-and-comment rulemaking."[93] Our letter further explained to the State that, "we are working towards meeting our legal obligations that have resulted from our January 2013 partial disapproval action for Utah's May 2011 regional haze SIP." EPA comment letters are intended to help improve any SIP revision that is under development, but they do not constitute agency action on that SIP revision or constitute any assurance of positive action on that revision upon submission and review. Instead and always, EPA has to formally discharge its responsibilities to review any SIP submittal. Moreover, the CAA does not require EPA to participate in state proceedings related to a state's SIP submission, nor does it preclude EPA from carrying out its statutory duty to disapprove an inadequate SIP if EPA does not voice concerns during state proceedings. The CAA requires EPA to issue a FIP when states have not met their obligations under the CAA. Therefore, EPA is promulgating this FIP to fill the regulatory gap created by the partial disapproval of Utah's SIP submittals. Despite the existence of a FIP, the State retains its authority to submit future regional haze SIPs consistent with CAA and RHR requirements; we do not discount the possibility of a future, approvable SIP submission that results in the modification or withdrawal of the FIP.

C. Reasonableness Standard

Comment: One commenter asserted that EPA arbitrarily and capriciously applies two inappropriate standards to the Utah SIP proposal. The commenter stated that, in an attempt to replace Utah's determination with its own, EPA imposes a "Reasonableness Standard" without concluding the Utah SIP contains data or methodological flaws—the limited circumstances under which courts have upheld use of this standard—and also imposes a "Complexity of Evaluation" standard which finds no support in the CAA or applicable regulations.

The commenter also asserted that EPA is prohibited from imposing additional requirements upon its approval/disapproval of a SIP that do not qualify as "applicable requirements." EPA is not correct in its attempt in the proposed action to impose additional requirements on its evaluation of the BART Alternative and Utah SIP that are different than the applicable BART alternative requirements.

1. Reasonableness Standard –EPA asserts that Utah "has several options for making the greater reasonable progress determination [and it] elected to use two separate approaches."[94] See 81 FR at 2006. EPA further states that it will evaluate both of those approaches in deciding whether to approve the Utah SIP. EPA then makes the blanket assertion that "the State's discretion in this area is subject to the condition that it must be reasonably exercised and that its decisions be supported by adequate documentation of its analysis." ("Reasonableness Standard.") See 81 FR at 2006. Although the use of words like "reasonable" and "adequate" have common sense appeal in the abstract, EPA may not apply this standard in a way that allows EPA to discard the state's discretion and instead impose EPA's own will.

In addition, the present circumstances regarding the SIP proposal are far different than those circumstances in which courts have upheld EPA's use of a similar Reasonableness Standard in other regional haze settings. For example, in *North Dakota* v. *EPA,* 730 F.3d 750, 760 (8th Cir. 2013), the court allowed EPA's use of the Reasonableness Standard under those circumstances where the state's BART determination contained "data flaws that led to an overestimated costs of compliance." Also, *Oklahoma* v. *EPA,* 723 F. 3d 1201, 1212 (10th Cir. 2013) reached a similar conclusion based on "methodological flaws."

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[90] Rebuttal Testimony of Cathy S. Woolums, at 26. (June 30, 2011). (Available in the docket at *https://www.regulations.gov/#!documentDetail;D=EPA-R08-OAR-2015-0463-0167*).

[91] Utah's Effective rule explains that "[w]hile Utah has chosen to meet the NO_X BART requirement through alternative measures . . . the enforceable emission limits for both NO_X and SO_2 established in the approval orders and in the SIP for the four EGUs also met the presumptive emission rates for both NO_X and SO_2 established in Appendix Y independently of the alternative program." Effective Rule at page E–12, Section XX, p. 168 (adopted by the Board on June 3, 2015), available in the docket at *https://www.regulations.gov/#!documentDetail;D=EPA-R08-OAR-2015-0463-0002.* The presumptive emission limits in the BART Guidelines are rebuttable. The presumptive emission limits apply to power plants with a total generating capacity of 750 MW or greater insofar as these sources are required to adopt emission limits at least as stringent as the presumptive limits, unless after considering the five statutory factors, the State determines that the presumptive emission limits are not appropriate.

[92] Congress required EPA to promulgate regulations to assure "reasonable progress" toward meeting the national goal and compliance with section 169A. The regulations require the submission of regional haze SIPs for states with Class I areas within their borders and states whose emissions "may reasonably be anticipated to cause or contribute to any impairment of visibility" in a Class I area outside their borders. 42 U.S.C. 7491(b)(2), 7491(e)(2). All SIPs must include "enforceable emission limitations and other control measures, means, or techniques . . . as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements of [the Act]." CAA section 110(a)(2)(A). Regional haze SIPs must include emission limits, compliance schedules, and other measures "as may be necessary to make reasonable progress toward meeting the national goal." 42 U.S.C. 7491(b)(2).

[93] Letter from Carl Daly to Bryce Bird, Re. EPA Region 8 Comments on Utah's February 2015 Draft Regional Haze SIP Revision, at 1 (May 1, 2015). (Available in the docket at *https://www.regulations.gov/#!documentDetail;D=EPA-R08-OAR-2015-0463-0160*).

[94] As explained below [referring to PacifiCorp's comment document], EPA is simply wrong in concluding that Utah used two separate approaches to demonstrate greater reasonable progress. Therefore, EPA's stated basis for imposing the Reasonableness Standard does not support EPA's effort to do so.

In the case of the SIP proposal, however, EPA proposes to approve the BART Alternative based on compliance with the applicable BART alternative requirements[95] and without also concluding that the BART Alternative contains "data flaws" or "methodological flaws." Therefore, the factual bases for allowing EPA to apply a Reasonableness Standard do not exist in regard to the BART Alternative and EPA should not attempt to apply such a standard here—particularly as a basis for rejecting the BART Alternative.[96]

2. Complexity of Evaluation Standard—EPA also is wrong in its attempt to count among applicable requirements the unsupported conclusion that the "complexity of our evaluation" somehow necessitates EPA soliciting comments not only on the SIP proposal, but also on the competing FIP proposal. See 81 FR 2006.[97] Even taking at face value the assertion that analyzing the Utah SIP is "complicated," that alone does not require EPA to evaluate the Utah SIP differently than any other regional haze SIP, nor does it justify EPA in presenting dueling co-proposals.[98] In other words, EPA has simply conjured up this new "complexity" requirement[99] out of thin air in an attempt to support its offering of the competing FIP proposal. EPA is acting arbitrarily and without legal authority by seeking comment on the FIP proposal based on what EPA calls the "complexity of our evaluation" and for this reason EPA should withdraw the FIP proposal and approve the SIP proposal as proposed.

Response: We disagree with most of these comments. First, we disagree that we have used a "reasonableness standard" in a manner that is inconsistent with our prior actions or as a way to limit the State's discretion. As discussed elsewhere, EPA has a duty to review Utah's regional haze SIP, including its BART Alternative, for compliance with the applicable requirements of the CAA and the RHR. Based on our review of the SIP, we proposed to determine that certain elements of Utah's regional haze SIP met the applicable requirements, and we proposed to approve those elements. However, for the reasons explained in detail in our proposed action and elsewhere in this document, we have concluded that, with regard to other elements, the State did not exercise its discretion in a reasonable manner, *i.e.,* in a manner consistent with the requirements and goals of the CAA and RHR. Based on these findings, we are required to partially disapprove Utah's regional haze SIP submittal.

As discussed in detail elsewhere, the CAA provides EPA with the authority to review and reject an inadequate regional haze SIP submittal. *Oklahoma* v. *EPA,* 723 F.3d 1201, 1207–08 (10th Cir. 2013) (EPA may not approve a submittal that does not adhere to applicable statutory and regulatory requirements). Contrary to the commenter's assertions, our analysis and decision here is entirely consistent with the *North Dakota* and *Oklahoma* decisions. The RHR requires a state to demonstrate that its BART alternative achieves greater reasonable progress than BART, 40 CFR 51.308(e)(2), and Utah chose to make this demonstration using a weight-of-evidence analysis. In our review, EPA found a number of flaws in this analysis. Based on this evaluation and findings as detailed in Section I.B.1 of this document and in our RTC document, we determined that, on balance, the evidence does not show that the Alternative clearly achieves greater visibility benefits than BART.

Second, we disagree with the assertions regarding creation of a new complexity standard. The commenter misunderstands and misconstrues our proposed action. We did not create a new complexity standard, rather we explained that we were considering complex information and that it was a close call for EPA to decide whether the evidence presented by the State clearly demonstrated that the BART Alternative would achieve greater reasonable progress than BART (the complexity of our evaluation leads us to propose and solicit comment on two conclusions and courses of action because several of the metrics *appear to* support the State's analyses, while others do not appear to support the Alternative).[100] Contrary to the commenter's assertions, we merely explained that the information in the State's SIP submittal was complex; we did not create a new standard by which to evaluate SIP submittals. Our proposed action clearly explained that some metrics appeared to support approval, while others metrics appeared to support a disapproval.

Therefore, given that EPA's evaluation of the information before us presented a close call, and in order to provide a fair and meaningful process for *all* members of the public, we used the co-proposal approach. This approach provided an opportunity for the public to comment on both potential courses of action, *i.e.,* approval or disapproval of the State's BART Alternative. Recognizing the information before the Agency was possibly susceptible to both interpretations, our two proposed conclusions and courses of action were as follows: "(1) The State's submittal meets the test above and we approve the BART Alternative; or (2) the State's submittal falls short of meeting this test and we disapprove the BART Alternative and promulgate a FIP for NO_X BART."

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[95] *See* generally 81 FR 2004, 2021–26.

[96] This is not to say that EPA lacks any role in reviewing and approving the Utah SIP. Indeed, the latest court to weigh in on EPA's review authority makes clear that "Congress intended that EPA, not the states alone, ultimately ensure that state determinations as to regional haze comply with the [Clean Air] Act. . . ." Arizona ex rel. Darwin v. EPA, Nos. 13–70366, 13–70410, 2016 U.S. App. LEXIS 3196, at *19–20 (9th Cir. Feb. 24, 2016). Although PacifiCorp agrees that EPA has a role to play in making sure the Utah SIP complies with the CAA and applicable requirements, it also notes that EPA must do so in a way that does not undermine the role of states like Utah to which "Section 169A [of the CAA] gives. . .substantial responsibility in determining appropriate BART [and BART Alternative] controls." The court goes on to make clear that "EPA may not disapprove reasonable state determinations that comply with the relevant statutory and regulatory requirements." *Id.* at *22. Such is the case with the Utah SIP.

[97] EPA attempts to further support this contrived "complexity" requirement by repeatedly stating that such a requirement exists, as if repetition alone somehow can bring an imaginary requirement into existence (*i.e.,* "In light of the variety of metrics Utah used, this is a complicated analysis. . . ;" "The complexity of our evaluation leads us to propose and solicit comments on two conclusions and two courses of action . . . ;" "Given the complexities in evaluating these co-proposals, EPA wants to ensure that our final decision is based on the best and most currently available data and information, and is taken with the fullest possible consideration of public input.") See 81 FR 2004, 2006.

[98] The Tenth Circuit Court of Appeals, which considered whether EPA's approval of a BART Alternative for SO_2 emissions was appropriate, did not conclude that EPA's analysis of the alternative program was, by its nature, more complicated than a BART analysis. See generally WildEarth Guardians v. EPA, 770 F.3d 919 (10th Cir. 2014).

[99] EPA further attempts to justify its rationale for considering the FIP proposal by asserting, as explained in footnote 3, the need to "ensure that our final decision is based on the best and most currently available data and information, and is taken with the fullest possible consideration of public input." EPA already is charged with ensuring that any final decision is based on the best current data and information available. See 71 FR 60612, 60622 (Oct. 13, 2006) (final rule on revisions to provisions governing alternative source-specific BART determinations); see also 5 U.S.C. 706(2). EPA already is required to make a decision based on the fullest possible consideration of public input. See 5 U.S.C. 553(c). Re-stating these fundamental principles does not allow EPA to bootstrap itself into also considering a competing coproposal (the FIP proposal) when the SIP proposal already meets all Applicable BART Alternative Requirements as EPA itself has proposed to conclude. Arizona ex rel. Darwin at *22 (stating that "EPA may not second-guess reasoned, legally compliant state decisions") (internal citations and quotations omitted).

[100] 81 FR 2004, 2006 (Jan. 14, 2016) (emphasis added).

We exercised our rulemaking discretion and structured the action using the co-proposal approach so that our action would enable all interested parties to have the opportunity to provide meaningful and timely comment on either or both approaches. In structuring the action in this way, the interested public had notice of the proposals under consideration and whether they had interests at stake. This balanced approach was fair in that it provided all interested parties with the options EPA contemplated in taking final action, as well as providing an opportunity to comment on the full range of potential actions. The commenter cites to no CAA provision that restricts EPA's authority to present co-proposals. EPA often provides alternative approaches for final Agency action in our SIP rulemaking proposals, as we did here. Additionally, even assuming that EPA's proposed action on the Utah regional haze SIPs articulated new "complexity" grounds for evaluating a regional haze SIP, the proposed action provided the public with the opportunity to comment. As evidenced by the commenter's submission, the commenter had the opportunity to provide input on this purported new standard to evaluating the Utah regional haze SIP and to identify any concerns associated with the statements at issue. Therefore, even if we had created a new complexity standard, which we did not, it would have been properly proposed and applied in this instance.

As explained above, the EPA proposal identified several weaknesses and flaws in the State's SIP submittal in the proposed rulemaking,[101] and as explained in this final action, other commenters have made us aware of additional weaknesses and uncertainties in the SIP submittal.[102] Therefore, EPA is finalizing our co-proposal to disapprove the BART Alternative and promulgate a FIP for NO_X BART, which this commenter recognizes EPA has a role and authority to do.

Furthermore, as explained elsewhere, we appreciate and clarify in this final action that the State did not intend to have its BART Alternative evaluated under both the 40 CFR 51.308(e)(2) and section 308(e)(3) tests. We, therefore, based our final action on our evaluation of the State's submittal under § 51.308(e)(2)'s weight-of-evidence test.

Finally, regarding the commenter's cross-reference to comments dated August 26, 2013, we explained in our final action in the Wyoming regional haze rulemaking that we disagreed with the comments in that context and we continue to disagree here.[103]

D. Compliance With 40 CFR 51.308

Comment: Two commenters noted that EPA's FIP proposal is unnecessary because EPA already found Utah is making the required "reasonable progress." The goal of the RH program is to make "reasonable progress" towards the statute's national visibility goal. Accordingly, EPA promulgated regulations "to assure . . . reasonable progress toward meeting" the national visibility goal, section 7491(b)(2), and mandated that EPA's regulations contain "such emission limits, schedules of compliance and other measures as may be necessary" to assure such progress towards meeting that goal, "including" a requirement that states make BART determinations. Id. As EPA has stated, "BART is one component of long term strategies to make reasonable progress." Regional Haze Regulations and Guidelines, 70 FR 39137.

Because BART's purpose is to make reasonable progress, EPA adopted regulations exempting states from making BART determinations if they can show that other measures for large stationary sources will achieve greater reasonable progress. 40 CFR 51.308(e)(2) (2012). EPA defended those regulations in court by arguing that BART is one of a number of "emission limits, schedules of compliance and other measures" that "must" be included in a SIP '"as may be necessary to make reasonable progress toward national visibility goals.' " *Ctr. for Energy and Econ. Dev.* v. *EPA*, 398 F.3d 653, 659–60 (D.C. Cir. 2005) (confirming BART is but one measure for achieving "reasonable progress"); *Cent. Arizona Water Conservation Dist.* v. *EPA*, 990 F.2d 1531, 1534 (9th Cir. 1993) (same). If an alternative can better achieve those goals, EPA has stated that BART would not be "necessary to make reasonable progress." *Id.* The court agreed with EPA's analysis, although it overturned EPA on other grounds. *Id.* As the court said, "the focus of the Clean Air Act was to achieve 'actual progress and improvement in visibility,' 42 U.S.C. 7492(b), not to anoint BART the mandatory vehicle of choice." *Id.* at 660.

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[101] Our proposal evaluated the State's use of the information from the metrics and identified weaknesses and flaws, for example: (1) The State's characterization of the 98th percentile modeling results that did not support its BART Alternative, was inconsistent with EPA's interpretation of and reliance on that metric; (2) the comparison of the results from the total annual emissions reductions was inconsistent with how we have interpreted our regulations; (3) the results from the modeling for the number of days the Alternative provided significant visibility impairment showed mixed results, with some results favoring the Alternative, while other results did not support the Alternative; (4) the annual average metric only marginally supported the Alternative, and showed less or equal visibility at four of nine Class I areas; and (5) the energy and non-air quality and cost metrics do not have a direct bearing on whether the Alternative achieves greater reasonable progress.

[102] Our RTC document provides details on the additional weaknesses and uncertainties that commenters brought to our attention.

[103] "As explained in our proposed rulemaking for section 51.309(d)(4)(viii), we explained that the provision 'is intended to clarify that if EPA determines that the SO_2 emission reductions milestones and backstop trading program submitted in the section 51.309 SIP makes greater reasonable progress than BART for SO_2, this will *not* constitute a determination that BART for PM or NO_X is satisfied for any sources which would otherwise be subject to BART for those pollutants' (emphasis added). 70 FR 44169 (Aug. 1, 2005). EPA does not interpret this rule to mean that there are different BART requirements for section 308 and 309 regional haze SIPs. EPA's rulemaking made no finding that BART determinations conducted for a state submitting a SIP under section 51.309 should be conducted any differently than a state submitting a FIP under only section 308. The use of the word 'necessary' in section 51.309(d)(4)(viii) was to explain that some states may have BART NO_X emission limitations, while others may not. As already explained elsewhere in proposal and our response to other comments, Wyoming did not conduct a proper evaluation of the five statutory factors, as required by 40 CFR 51.308(e)(1)(ii)(A) and section 169A(g) of the CAA.

EPA also disagrees with the commenter's assertion that a BART submission is discretionary. 40 CFR 51.309(d)(4)(viii) is clear in that the implementation plan 'must' contain BART requirements. The proposed rulemaking explained that the provision that provides that '[a]ny such BART provisions may be submitted pursuant to either Section 51.308(e)(1) or 51.308(e)(2),' was included to 'allow States the flexibility to address these BART provisions either on a source-by-source basis under Section 51.308(e)(1), or through an alternative strategy under Section 51.308(e)(2).' 70 FR 44169 (Aug. 1, 2005).

Moreover, EPA's proposal made clear that '[i]n limited circumstances, it may be possible for a State to demonstrate that an alternative program which controls only emissions from SO_2 could achieve greater visibility improvement than application of source-specific BART controls on emissions of SO_2, NO_X and/or PM. We nevertheless believe that such a showing will be quite difficult to make in most geographic areas, given that controls on SO_2 emissions alone in most cases will result in increased formation of ammonium nitrate particles.' 70 FR 44169 (Aug. 1, 2005). Wyoming's RH SIP does *not* include a demonstration that the backstop SO[2] trading program under Section 51.309 achieves greater visibility improvement than application of source-specific PM BART controls. Therefore, Wyoming's Section 51.309 SIP does not provide the adequate level of visibility improvement to meet the BART requirements

With respect to the relationship of BART and requirements for reasonable progress under *40 CFR 51.308*, EPA interprets the reasonable progress requirements to apply to BART sources. As explained in our guidance, due to the similarity of the BART and reasonable progress factors, states may reasonably rely on their BART determinations to show reasonable progress for those sources for the first planning period. However, BART is an independent requirement of the statute and the RHR. We have disapproved certain BART determinations by Wyoming not due to a failure to make reasonable progress, but due to a failure to consider the BART factors appropriately." 79 FR 5032, 5098, 5099 (Jan. 30, 2014).

As EPA recognizes, in some circumstances no BART controls may be necessary to make reasonable progress. It follows that in other circumstances, depending on a state's reasonable-progress goals and expected non-BART emission reductions, BART controls of varying stringency may be necessary. Consistent with this goal, EPA has approved Utah's "reasonable progress" determination for its RH SIP in its entirety. *See* "Approval, Disapproval and Promulgation of State Implementation Plans; State of Utah; Regional Haze Rule Requirements for Mandatory Class I Areas Under 40 CFR 51.309," published at 77 FR 74355, 74367–68 (Dec. 14, 2012). EPA found that "the State met all reasonable progress requirements for the Class I areas," including by implication any required NO_X BART limits. In fact, EPA stated that Utah's 2008 RH SIP, including BART controls identified in that 2008 RH SIP, would result in "a significant decrease in stationary source NO_X and SO_2 emissions." *Id.* EPA further found that the NO_X BART controls adopted by Utah for the Hunter and Huntington EGUs at issue would decrease NO_X emissions by "6,200 tons [annually] between 2002 and 2018." *Id.* Therefore, EPA acknowledged that Utah's NO_X BART limits and controls are all that are required to achieve "reasonable progress," and no further NO_X BART requirements should be imposed by EPA through its FIP proposal.

Thus, EPA cannot validly judge a state's BART determination outside of its reasonable progress context. *Owasso Indep. Sch. Dist. No. I–011* v. *Falvo*, 534 U.S. 426, 434 (2002) ("the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.").

Response: EPA disagrees with these comments. The commenters appear to be asserting that, since EPA approved Utah's 2011 SIP submission as meeting the reasonable progress requirements of 40 CFR 51.309 with regard to SO_2, no further controls are necessary to meet the RHR's requirements for NO_X and PM. However, this assertion ignores our statements in the BART Alternatives rulemaking that an EPA determination that a backstop trading program satisfies a state's reasonable progress obligations for SO_2 under 40 CFR 51.309 does not satisfy that state's obligation to address NO_X and PM requirements under 40 CFR 51.308(e)(1) or (2). In this rulemaking, EPA proposed amendments to the stationary source NO_X and PM provisions within § 51.309 precisely in order to "clarify that if EPA determines that the SO_2 emission reductions milestones and backstop trading program in the § 51.309 SIPs makes greater reasonable progress than BART for SO_2, this will *not* constitute a determination that BART for PM or NO_X is satisfied for any sources which would otherwise be subject to BART for those pollutants."[104] The final rulemaking reinforced that a reasonable progress determination for SO_2 under § 51.309's backstop trading program does not satisfy the emission reductions requirements for non-SO_2 pollutants.[105]

We also took this position in another recent regional haze action, in which we found that the state's approved SO_2 alternative under § 51.309 did "not provide the adequate level of visibility improvement to meet the [non-SO_2] BART requirements."[106] We then reiterated that "BART is an independent requirement of the statute and the RHR."[107] Our statements in both the national and regional contexts make it clear that a reasonable progress determination for an SO_2 backstop trading program under § 51.309 does not relieve a state of its obligation to satisfy NO_X and PM BART. EPA thus *can* judge a state's BART determination outside the reasonable progress context, as they are independent requirements.

The commenters' claim that EPA's approval of Utah's § 51.309 program in our December 2012 final action means that the State met its reasonable progress requirements "in its entirety" is thus clearly incorrect. In that action we determined that the State met the requirements of § 51.309 and therefore satisfied its reasonable progress obligation *with regard to the particular pollutants covered in the State's alternative, i.e.,* SO_2. This determination has no bearing on the State's independent NO_X and PM obligations. To comply with the RHR, the state must still address any BART obligations for pollutants not included in the BART alternative analysis and therefore not covered by the "better than BART" determination.

EPA similarly disagrees that it acknowledged that the NO_X controls in Utah's 2011 SIP submission are all that are required to achieve reasonable progress and that EPA should therefore not require further NO_X BART requirements. As explained earlier, EPA's determination that Utah's 2011 submission satisfied reasonable progress requirements does not constitute implicit evaluation and action on Utah's NO_X and PM SIP submittal as meeting the BART requirements. Furthermore, the commenter overlooks EPA's explicit disapproval of Utah's NO_X and PM BART determinations in our December 2012 partial approval/disapproval.[108] EPA's disapproval of Utah's NO_X and PM control determinations necessarily precludes finding that these same controls are all that are required to satisfy the RHR's requirements. EPA is thus required to promulgate a NO_X BART FIP, which we are now doing. Commenters also take EPA's statements regarding the quantity of anticipated NO_X reductions from Utah's rejected BART determination out of context. These statements were offered as reasons why Utah satisfied the RHR's requirement to address impacts on Class I areas in other states by achieving previously agreed upon emission reductions, which is a separate consideration from whether the State has satisfied its independent NO_X and PM BART obligations.

EPA also disagrees that the statements in the cited cases have any bearing on this action. In *Center for Energy and Economic Development* v. *EPA* (*CEED*),[109] the issue was whether EPA's BART alternative provisions in § 51.309 were consistent with CAA section 169A(b)(2) given that they used a methodology for establishing the BART benchmark that the D.C. Circuit had previously vacated in *American Corn Growers Ass'n* v. *EPA*.[110] As part of its challenge to EPA's BART alternative provisions, CEED argued that section 169A(b)(2) requires all states' SIPs to include BART, meaning EPA could not allow BART alternatives in place of source-specific BART. EPA argued that section 169A(b)(2) allows either BART or an alternative to BART submitted pursuant to § 51.309 if that alternative would achieve greater reasonable progress than BART, *i.e.*, if the alternative is "better than BART." The statements the commenter cites express EPA's view on the narrow issue of whether and when we may allow states to substitute an SO_2 trading program for source-specific BART under § 51.309. Because these statements address only the relationship between BART and BART alternatives for SO_2 under § 51.309; they have no bearing on whether we believe a state's submission of an SO_2 trading program satisfies its independent obligation to address NO_X and PM, as these obligations were not at issue in this case.

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[104] 70 FR 44154, 44169 (Aug. 1, 2005) (emphasis added).

[105] 71 FR 60612, 60626 (Oct. 13, 2006).

[106] 79 FR 5032, 5099 (Jan. 30, 2014) (final partial approval/partial disapproval of Wyoming regional haze SIP submission).

[107] *Id.*

[108] 77 FR 74355, 74357 (Dec. 14, 2012).

[109] 398 F.3d 653 (D.C. Cir. 2005).

[110] 291 F.3d 1 (D.C. Cir. 2002).

In our December 14, 2012 action we approved Utah's BART Alternative for SO_2 under 40 CFR 51.309, finding that it achieved greater reasonable progress than SO_2 BART. As explained earlier, this determination has no bearing on Utah's outstanding NO_X and PM BART obligations. We, therefore, disagree that today's action to address these obligations is unnecessary.

Comment: Several commenters asserted that Utah's BART Alternative does not achieve greater reasonable progress based on the "clear weight-of-evidence." Utah's Regional Haze SIP also must be rejected under 40 CFR 51.308(e)(2)(i)(E) because it does not achieve "greater reasonable progress" based on the "clear weight-of-evidence."[111]

At the outset, Utah's proposed reliance on the "clear weight-of-evidence" test is improper. In promulgating regulations allowing for the test, 40 CFR 51.308(e)(2)(i)(E), offered the following example of when the test might be appropriate: "(1) The alternative program achieves emissions reductions that are within the range believed achievable from source-by-source BART at affected sources, (2) the program imposes a firm cap on emissions that represents meaningful reductions from current levels and, in contrast to BART, would prevent emissions growth from new sources, and (3) the State is unable to perform a sufficiently robust assessment of the programs using the two pronged visibility test due to technical or data limitations."[112] None of those conditions are met here. Most importantly, Utah's BART Alternative does not drive any meaningful reductions from "current levels" and does not prevent emissions growth from new sources, and Utah is not hindered by any technical or data limitations preventing a sufficiently robust visibility assessment. EPA further noted that "a weight-of-evidence comparison may be warranted" "when there is confidence that the difference in visibility impacts between BART and the alternative scenarios are expected to be large enough."[113] Here, as EPA correctly observed, even Utah's flawed modeling demonstrated the superiority of BART using the most relevant visibility metric and only minimal benefits of the BART Alternative compared with BART using other metrics.

Several commenters also raised concerns regarding emission shifting from the power plants covered by the SIP to existing sources that are not included in this SIP. They suggested that due to the nature of the electrical generation market, with the adjustments to the overall system to add capacity elsewhere to accommodate the Carbon power plant shutdown (and perhaps also to accommodate the emission limit reductions at the Hunter and Huntington power plants), those shifts in capacity could result in increases in emissions at power plants outside the BART Alternative. The commenters further suggested that if those emission increases had been considered in the State's weight-of-evidence analysis, the BART Alternative may not provide greater reasonable progress than BART if the emission reductions assessment under the Alternative are not permanent and were to shift to other power plants. As an example, one of the commenters provided an analysis for a Utah power plant (not covered by the BART Alternative) that based on its proximity to the nine Class I areas analyzed under the BART Alternative, if emission increases were to occur at that plant the increases could impact visibility impairment at the Class I areas. Other commenters expressed concern that the lost capacity from the BART Alternative sources could shift to new sources, and explained that the emissions from new sources are not evaluated in the State's weight-of-evidence analysis. One commenter suggested that this Alternative appears to be more like a "trading" program and that other regulations apply. One commenter expressed concern that a non-BART source is included in the BART Alternative, and further, that not all the sources in the State that are part of this source category are included.

Response: We agree in part and disagree in part with these comments. First, as explained elsewhere, we agree with the commenter that the State's analysis for the BART Alternative does not show that the Alternative clearly achieves greater visibility benefits than BART. Second, the four examples cited by the commenter from our RHR preamble were *examples,* rather than an exclusive list of circumstances under which a state may use a weight-of-evidence analysis. Therefore, the State was not required to fall into one of these categories in order to select the weight-of-evidence approach to support its BART Alternative. Third, we disagree that emission reductions must occur from current levels, because, consistent with the RHR, the baseline date for regional haze SIPs is 2002.[114]

Next we respond to the commenters' concerns about potential shifting of production and emissions from the sources in the BART Alternative to sources outside the BART Alternative. We acknowledge that the State's BART Alternative has the following characteristics: (1) It includes all the BART sources in the State; (2) it accounts for emission reductions from a non-BART source; and (3) it includes some, but not all, sources in the source category within the State. The RHR provides that BART alternative programs may include non-BART sources.[115] We disagree with commenters that suggested the RHR trading requirements apply to the Utah BART Alternative.[116] The RHR trading provisions apply to SIPs that establish a cap on total emissions from sources that are subject to the BART program, and further require the owners and operators of the sources to hold allowances to purchase, sell, and transfer allowances. Utah's SIP contains rate-based emission limits on the sources that are subject to the BART Alternative and therefore does not include a cap on emissions or trading provisions. Therefore, the Utah SIP does not contain the elements of a trading program as described in the RHR, which include provisions to prevent significant emission shifting.[117]

Although the State's SIP explained that the Carbon power plant had already closed and electricity generated from the Carbon power plant has been replaced (and the associated costs already have been absorbed by Utah rate payers and those in other states served by PacifiCorp),[118] the SIP submittal neither identified what electrical generating facilities increased capacity to accommodate the Carbon shut down, nor did it provide an analysis of whether the capacity replacement resulted in increases in visibility impairing pollutants. Furthermore, in addition to seeking and receiving authorization to recover costs associated with retirement of the Carbon plant, the Company also received authorization from state utility commissions to recover additional costs, including "installation of equipment necessary to ensure voltage stability, along with various communications upgrades and protection and control equipment."[119] It is unclear whether the activities associated with these additional costs resulted in capacity and emissions shifting and increased visibility impairment at the affected Class I areas. Therefore, while the record before us indicates that capacity has shifted, it is unclear how the shift was accommodated, and whether there are any emission increases and associated visibility impairment.[120]

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[111] 40 CFR 51.308(e)(2)(i)(E).

[112] 71 FR 60612, 60621 (Oct. 13, 2006).

[113] *Id.* at 60622.

[114] *See* Memorandum from Lydia Wegman and Peter Tsirigotis, 2002 Base Year Emission Inventory SIP Planning: 8-hr Ozone, $PM_{2.5}$, and Regional Haze Programs (November 18, 2002).

[115] The preamble to the RHR provides for inclusion of BART and non-BART sources in a BART alternative. 64 FR 35714, 35743 (July 1, 1999).

[116] 40 CFR 51.308(e)(2)(E)(v) (containing requirements for a state to demonstrate that a trading program prevent any significant, potential shifting within the state of production and emissions from the sources in the program to sources outside the program).

[117] *Id.*

[118] Utah Staff Review Report at 27.

It is therefore unclear whether the shift in capacity as a result of the Carbon plant retirement results in increased emissions and visibility impairment at the affected Class I areas. Because the record lacks information on these questions, we agree with the commenters that there is additional uncertainty as to whether the BART Alternative is better than BART.

E. Overarching Comments on BART Alternative Demonstration

Comment: The State of Utah commented that EPA should approve the option that Utah developed in close consultation with EPA and not the option that Utah was not even aware was being prepared or under consideration until it was signed by the Regional Administrator. Utah worked closely and in good faith with the EPA and the FLMs to evaluate and implement the appropriate controls for improving visibility. Up to the point of the current proposal, the EPA has indicated to Utah that the alternative to BART approach and analysis were acceptable. During the RH SIP development process, Utah and EPA worked as regulatory partners—Utah working closely and extensively with EPA's staff to ensure that Utah's BART Alternative was approvable. EPA's concurrence with Utah's RH SIP proposal is also supported by EPA's comments submitted during the state rulemaking public comment period on the current revision of the Utah's RH SIP. EPA did not point to any substantive flaws in Utah's RH SIP, but only requested minor clarifications and revisions in its 3-page comment letter.

Response: While we agree that EPA worked in close consultation with Utah on the BART Alternative within the limitations of what the State and PacifiCorp were willing to offer in the plan, EPA is not required to approve the option developed by Utah. As stated elsewhere in this document, EPA's comment letter on the State's proposed SIP explicitly explained the following: "[p]lease note that we will only come to a final conclusion regarding the regional haze program for Utah when we take action on the program through our own public notice-and-comment rulemaking."[121] Our May 1, 2015 letter further explained to the State that, "[i]n addition, we wish to inform you that we are working towards meeting our legal obligations that have resulted from our January 2013 partial disapproval action for Utah's May 2011 regional haze SIP."[122] EPA's assistance to states and our comment letters are intended to be helpful to the improvement of any SIP revision that is under development, but they do not constitute agency action on that SIP revision or constitute any assurance of positive action on that revision upon submission and review.

Additionally, the State's efforts to involve the FLMs did not adequately meet the requirements for FLM consultation in developing plan revisions. The State could have satisfied the consultation requirements by providing more time for FLM review so that the FLMs would have received the full number of 60 days for their review. However, in developing the co-proposals, consulting with the FLMs, and by taking this final action, EPA has considered the FLMs' concerns.

Comment: Several commenters asserted that both Utah and EPA imply that nitrate formation in non-winter months is not significant,[123] or that NO_X reductions will not meaningfully reduce nitrates in non-winter months.[124] Both are untrue. Based on IMPROVE data, light extinction attributable to ammonium nitrate in non-winter months is roughly 20% of that attributable to ammonium sulfate. Despite the preferential formation of ammonium sulfate year round and higher ammonium nitrate formation in winter months, it is clear that significant levels of ammonium nitrate also form in non-winter months, and that these are likely to be lowered by reductions in NO_X emissions. Furthermore, while EPA notes that wintertime conditions favor nitrate formation (versus non-winter),[125] this is accounted for in modeling and cannot be used to discount those results.

Response: We partially agree with the comment. While EPA did not suggest that nitrate in non-winter months is not significant, IMPROVE monitoring data do show that nitrate light extinction is highest in winter and substantially smaller in the other seasons. For example, in 2014, the most recent year of IMPROVE data available at the Canyonlands monitor, nitrate contributed an average of 31% of total light extinction in December to February compared to an average of 5% of total light extinction from March to November. In 2013, nitrate contributed an average of 45% of total light extinction in December to February compared to an average of 7.5% of total light extinction from March to November. By contrast, sulfate light extinction is relatively constant across the four seasons.[126]

Nonetheless, overall nitrate extinction at the affected areas is significant, particularly on the 20% worst days. For example, at Canyonlands on the 20% worst days, nitrate contributed 33% and 17% of total extinction in 2013 and

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[119] *The Application of Rocky Mountain Power for Approval of a General Rate Increase,* No. 20000–446–ER–14, Wyoming Public Service Commission, (Jan. 23, 2015) (Findings of Fact, Conclusions of Law, Decision and Order Nunc Pro Tunc) (Available in docket at *https://www.regulations.gov/#!documentDetail;D=EPA-R08-OAR-2015-0463-0167*). An order from the Idaho Public Commission also discussed the impacts from Carbon's retirement on the transmission system and noted that "[t]he Company states that retiring Carbon may pose a complication with potential transmission system impacts." *See The Application of PacifiCorp DBD DBA Rocky Mountain Power,* Case No. PAC–E–12–08, Order No. 32701, at 1, Idaho Public Utilities Commission (Dec. 27, 2012) (Available in the docket at *https://www.regulations.gov/#!documentDetail;D=EPA-R08-OAR-2015-0463-0167*).

[120] Utah's BART Alternative has the characteristics of an "open market" program where some, but not all, sources in a source category are covered by the SIP measure. EPA Guidance, "Improving Air Quality with Economic Incentive Programs," at 48, 96, 112–118, EPA–452/R–01–001 (Jan. 2001), available at *https://www3.epa.gov/ttn/caaa/t1/memoranda/eipfin.pdf*); 77 FR 11928 (Feb. 28, 2012); 77 FR 46952 (Aug. 7, 2012).

[121] Letter from Carl Daly to Bryce Bird, Re. EPA Region 8 Comments on Utah's February 2015 Draft Regional Haze SIP Revision, at 1 (May 1, 2015). (Available in the docket at *https://www.regulations.gov/#!documentDetail;D=EPA-R08-OAR-2015-0463-0160*).

[122] *Id.*

[123] Utah Staff Review Report at 17, Exhibit 15. Winter months in this context are December, January, and February.

[124] 81 FR 2004, 2023 (EPA says that based on a computational model, "We propose to find that visibility benefits associated with NO_X reductions are much more likely to occur in the winter months because this is when aerosol thermodynamics favors nitrate formation").

[125] *Id.*

[126] See EPA spreadsheet entitled, Canyonlands IMPROVE Monitoring Data for 2013 and 2014 (Available in the in the docket).

2014, respectively. Given the focus of the reasonable progress provisions of the RHR on the 20% worst days, we consider the monitoring data for these days to be more informative than seasonal trends in monitoring data.

We also agree with the commenter that the modeling performed by Utah and EPA accounts for the fact that wintertime conditions favor nitrate formation (versus non-winter). In particular, the CALPUFF modeling performed by Utah and EPA both show that, while there will be some benefits from NO_X controls outside of the winter season, the largest benefits in nitrate reductions occur in winter months.[127] We have taken the strength of the modeling results for winter months into consideration; however, contrary to suggestions that visibility improvements during seasons of peak Class I area visitation should carry more weight, we have evaluated the visibility impacts throughout the entire year, regardless of the season and have given the most weight to those times when the sources in question have the largest impacts. In particular, as explained elsewhere in this document and our RTC document, we have given greater weight to the 98th percentile CALPUFF metric, which captures these highest impact days.

F. Cost of Controls

Comment: Several commenters submitted comments regarding the costs to install SCR at the Hunter and Huntington BART EGUs. PacifiCorp submitted a technical report developed by its consultant, Sargent & Lundy, which criticized numerous aspects of EPA's cost analysis developed by our contractor, Andover Technology Partners (ATP), including catalyst volume, SCR design, project and process contingency costs, and others. The conservation organizations' consultant reviewed PacifiCorp's cost analyses from 2012 and 2014 and provided comments about the validity of PacifiCorp's analyses. The National Park Service supported EPA's cost estimates in the proposed rule and indicated the estimates show that both the combined cost of LNB and SOFA plus SCR (SCR + LNB/SOFA) and the incremental cost of adding SCR to LNB/SOFA are cost-effective and represent BART. The conservation organizations also supported EPA's cost estimates in the proposed rule.

Response: EPA has provided a revised cost analysis to support our final rulemaking. We again used Andover Technology Partners (ATP) for conducting the analysis. We have carefully reviewed the analysis and determined that it appropriately estimates the costs to install SCR at Hunter and Huntington. Of particular note is that in our revised cost analysis, EPA has accepted both the catalyst volume and SCR design suggested by Sargent & Lundy. However, we continue to reject process and project contingency costs and other costs that are double counted, not permissible under the CCM, or are otherwise not justified. The final Andover report and spreadsheet provide further details regarding how each of these costs was addressed in the revised analysis supporting this rulemaking.[128] Also, in our RTC document, we have addressed the specific comments concerning the capital costs that Sargent & Lundy alleges that Andover incorrectly excluded from its analysis, as well as all other comments regarding our cost estimates.

We concur with the National Park Service's and conservation organizations' supportive comments regarding the cost effectiveness of SNCR and SCR. In addition, the revised cost effectiveness estimates that we prepared to support this final rule, when considered along with the other five BART factors, continue to support selection of SCR + LNB/SOFA as BART.

The conservation organizations' comments pertain to the costs that PacifiCorp submitted to the Utah Department of Air Quality, and which Utah included in its SIP submittal to EPA. However, EPA developed separate costs to support our FIP, and has updated those costs in support of our final action. Our RTC document contains additional detail concerning our consideration of these comments.

G. Comparison With Other Regional Haze Actions

Comment: Two commenters agreed with the comparisons we provided in our proposed rule to other BART determinations that EPA used to support our proposed FIP. One commenter disagreed with the comparisons. These comparisons included Cholla,[129] Hayden,[130] and Laramie River Station.[131] The commenter who disagreed asserted that different methodologies were involved in all three cases and that EPA failed to provide comparisons to other actions that did not support the FIP. The commenter provided additional examples from EPA actions in Florida, Montana, and Nebraska that they asserted do not support EPA's Utah FIP decision.

Response: We continue to find that the Cholla, Hayden and Laramie River Station comparisons are among the best to use considering the specifics of our Utah action. The commenter who disagreed with these comparisons did not show that it would make a significant difference to use precisely the same methodology in each of the determinations that EPA chose to rely on. Furthermore, we disagree that the methodology involved in the BART analyses necessarily must be precisely the same for each BART determination in order to use the determinations for comparison purposes. For example, a state may choose to use a slightly different methodology to analyze the BART factors and select BART, which is acceptable so long as the methodology is reasonable and consistent with the statute, RHR, and BART Guidelines. For details, please see the RTC document.

We also disagree that the cited BART determinations in Montana, Florida, and Nebraska are useful comparisons or show that our BART determination here is unreasonable. First, with respect to the Florida action, the cited NO_X BART determination at FPL's Manatee Plant involved two 800 MW oil and natural-gas fired steam turbines. 77 FR 73369, 73377 (Dec. 10, 2012) (proposal). As the two units were equipped with FGR, overfire air systems, staged combustion, LNB, and reburn, SCR was the only available additional control option identified. The total annualized cost of SCR at the two units would be $31 million, from which the state computed a dollar-per-deciview cost of $66 million/dv. *Id.* at 73377. Using these figures, the total (*i.e.* source wide) visibility improvements at the most impacted Class I area, Chassahowitzka NWA, would be 0.47 dv, which is considerably below the source-wide visibility improvement for SCR + LNB/SOFA at Hunter and Huntington of 2.948 dv and 3.848 dv, respectively.[132]

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[127] Both Utah and EPA CALPUFF modeling results can be viewed in or obtained from the EPA Region 8 offices by contacting the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

[128] Andover Technology Partners, *Cost of NO_X BART Controls on Utah EGUs to: EC/R Inc.* (May 13, 2016). Andover Technology Partners is a subcontractor to EC/R Incorporated.

[129] 77 FR 42834 (July 20, 2012) (proposal); 77 FR 72512, 72514–15 (Dec. 5, 2012) (final).

[130] 77 FR 18069 (Mar. 26, 2012) (proposal); 77 FR 76871 (Dec. 31, 2012) (final).

[131] 79 FR 5032, 5099 (Jan. 30, 2014) (final partial approval/partial disapproval of Wyoming regional haze SIP submission).

[132] See also our response to comments on existing controls and the baseline, in which we look at the cost and visibility benefits at Hunter and Huntington of SCR apart from the LNB/SOFA, to

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In addition, the Manatee Plant impacted only one other Class I area, Everglades NP, at nearly twice the distance of Chassahowitzka NWA. In comparison, Hunter and Huntington significantly impact nine Class I areas. Furthermore, the Manatee Plant received a permit to increase natural gas utilization from 5,670 MMBtu/hr to 8,650 MMBtu/hr, which would displace the use of oil and provide additional NO_X reductions. All of these must be considered when examining the state's conclusion that SCR would not be cost-effective for these units, which was primarily based on the dollar-per-deciview cost of $66 million/dv and not on the raw cost-effectiveness number of $3,776/ton. While we are not basing our BART determinations on the dollar-per-deciview metric, for purposes of comparison to Manatee, the dollar-per-deciview cost for Hunter and Huntington would be considerably less than at Manatee, about $23.7 million/dv and $15.8 million/dv, respectively, at the most impacted Class I area, and as mentioned earlier Hunter and Huntington impact many more Class I areas than Manatee.

With respect to the Montana action, EPA stated for PPL Colstrip Units 1 and 2, "we estimated the incremental cost effectiveness of SCR + SOFA (over SNCR + SOFA) to [be] $5,770/ton and $5,887/ton, respectively. Given these costs, we continue to find that SCR + SOFA is not justified *by the visibility improvement that would be provided.*" 77 FR 57864, 57889 (Sept. 18, 2012) (emphasis added). The commenter omits the emphasized language. The visibility improvements for the various NO_X control options for Colstrip Units 1 and 2 can be seen in our proposal action and in general are much lower than those for Hunter and Huntington. See 77 FR 23988, 24026–27, 24034–35 (Apr. 20, 2012). In particular, at Colstrip Unit 1, the visibility improvements from SCR + SOFA at the five impacted Class I areas (which is less than the nine impacted by Hunter and Huntington) ranged from 0.081 to 0.404 dv. At Colstrip Unit 2, the visibility improvements from SCR + SOFA at the same class I areas ranged from 0.091 dv to 0.423 dv. These values are all much less than for the Hunter and Huntington BART units. In any case, our NO_X BART determinations for Colstrip Units 1 and 2 were vacated by the Ninth Circuit Court of Appeals. *Nat'l Parks Conserv. Ass'n* v. *U.S. EPA,* 788 F.3d 1134 (9th Cir. 2014).[133] Finally, commenter's citation to the Nebraska proposal is fully addressed by our response to a similar comment on our Wyoming regional haze action. 79 FR 5032, 5178 (Jan. 30, 2014). Please refer to our RTC document for additional discussion of our comparisons to other BART determinations.

H. CALPUFF Modeling

Comment: We received many comments related to both EPA's modeling for the FIP and Utah's modeling for the BART Alternative. In particular, PacifiCorp and its consultant asserted that EPA failed to account for the margin of error in the CALPUFF model and other material limitations of CALPUFF. PacifiCorp also asserted that we should have used CALPUFF version 6.42 in our FIP analysis instead of version 5.8.4. We partially respond to these comments here. Our full responses are contained in our RTC document.

Response: We do not agree with the commenter's criticism of the use of CALPUFF. In promulgating the 2005 BART Guidelines, we responded to comments concerning the limitations and appropriateness of using CALPUFF. In 2005 we explained that CALPUFF is the only EPA-approved model for use in estimating single source pollutant concentrations resulting from the long range transport of primary pollutants. In addition, it can also be used for other purposes such as visibility assessments to account for the chemical transformations of SO_2 and NO_X. As explained earlier, simulating the effect of precursor pollutant emissions on $PM_{2.5}$ concentrations requires air quality modeling that not only addresses transport and diffusion, but also chemical transformations. CALPUFF incorporates algorithms for predicting both. At a minimum, CALPUFF can be used to estimate the relative impacts of BART-eligible sources. *We are confident that CALPUFF distinguishes, comparatively, the relative contributions from sources such that the differences in source configurations, sizes, emission rates, and visibility impacts are well-reflected in the model results.*[134]

EPA also recognized the uncertainty in the CALPUFF modeling results when EPA made the decision (in the final BART Guidelines) to recommend that states use the 98th percentile visibility impairment rather than the highest daily impact value. We made the decision to consider the 98th percentile primarily because the chemistry modules in the CALPUFF model are simplified and likely to provide conservative (higher) results for peak impacts. Since CALPUFF's simplified chemistry could lead to model over predictions, EPA recommended the use of the 98th percentile to avoid giving undue weight to the extreme tail of the distribution.[135] Therefore, in recognizing some of the limitations of the CALPUFF model, we determined that use of the maximum modeled impact may be overly conservative and recommended the use of the 98th percentile value. While recognizing the limitations of the CALPUFF model in the BART Guidelines preamble, EPA concluded that, for the specific purposes of the RHR's BART provisions, CALPUFF is sufficiently reliable to inform the decision making process.[136]

It is further worth noting that the CALPUFF model can both predict higher and lower visibility impacts compared to a photochemical grid model. For example, the 2012 ENVIRON report on *Comparison of Single-Source Air Quality Assessment Techniques for Ozone, $PM_{2.5}$, other criteria pollutants and AQRVs* found that CALPUFF's predictions of the highest 24-hr nitrate and sulfate concentrations were lower than those predicted by the CAMx photochemical grid model in some areas within the modeling domain.[137] Thus, while there is some uncertainty in the absolute visibility impacts and benefits due to the model and some of the simplifications and assumptions used in the BART Guidelines modeling approach, the relative level of impact has been a reliable assessment of the degree of visibility impacts and benefit from controls. Any uncertainties in meteorological conditions that govern the transport and diffusion of pollutants are less important in comparing impacts between two control scenarios, since the

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show that even if we agreed with this commenter that the baseline should reflect the installation of LNB/SOFA—which we do not—the selection of SCR as BART would still be reasonable. The numbers used there also compare favorably with Manatee.

[133] The same commenter notes that the Wyoming and Arizona BART determinations we used for comparison purposes are currently under litigation; however the commenter fails to note that the Montana BART determination they propose for comparison was actually litigated and vacated. With respect to the pending litigation over the Wyoming and Arizona BART determinations, there are other BART determinations such as Colorado's Hayden Station that are comparable, support our selection of SCR + LNB/SOFA, and are not under litigation.

[134] 70 FR 39122 (Jul. 6, 2005) (emphasis added).

[135] "Most important, the simplified chemistry in the model tends to magnify the actual visibility effects of that source. Because of these features and the uncertainties associated with the model, we believe it is appropriate to use the 98th percentile—a more robust approach that does not give undue weight to the extreme tail of the distribution." 70 FR 39104, 39121 (Jul. 6, 2005).

[136] 70 FR 39123 (Jul. 6, 2005).

[137] Comparison of Single-Source Air Quality Assessment Techniques for Ozone, $PM_{2.5}$, other Criteria Pollutants and AQRVs, ENVIRON, September 2012.

same effects will be included in both the base and the control scenario model simulations.

We also do not agree with the commenter's calculation of a "margin of error" for CALPUFF. The notion of a calculated "margin of error" is not part of any modeling guidance and has no legal or regulatory basis or applicability here. In addition, the commenter's suggestion that a 2012 report titled "Documentation of the Evaluation of CALPUFF and Other Long Range Transport Models Using Tracer Field Experiment Data", EPA–454/R–12–003 (ENVIRON Report) establishes a standard "margin of error" for CALPUFF is unfounded. The ENVIRON Report illustrated how well various types of modeling systems are able to capture regional transport. It does not provide any information about the accuracy of any models for predicting secondary $PM_{2.5}$ or visibility, nor does it indicate that the quantitative performance results provided are a presumptive globally applicable "margin of error." Rather, these results are simply a way to compare various modeling systems in terms of performance for skill in long range transport. Thus, we do not agree that the ENVIRON Report provides a presumptive margin of error that can be applied to the modeling results in Utah's SIP or EPA's FIP.

With regard to Utah's use of CALPUFF in its SIP revision specifically, we note that the State was not required to use CALPUFF for purposes of its BART Alternative Demonstration under 40 CFR 51.308(e)(2)(i). Utah or PacifiCorp could have used other EPA-approved models with more advanced chemistry and dispersion techniques to support the BART Alternative demonstration but chose not to do so.

With regard to our use of CALPUFF for purposes of the FIP modeling, as explained in more detail in our RTC document, the legal deadline for challenging EPA's recommendation to use CALPUFF in BART analyses has passed. Furthermore, although the EPA proposed revisions to 40 CFR part 51, appendix W, Guideline on Air Quality Models ("Guideline") in 2015, these proposed changes to the Guideline do not affect our recommendation in the 2005 BART Guidelines to use CALPUFF in the BART determination process.[138] Rather, as explained in the preamble to the proposed Guideline revisions, we consider it appropriate to continue using CALPUFF for BART determinations, given that the vast majority of BART determinations have been made using CALPUFF.[139]

In particular, for our FIP modeling, we used the current EPA-approved version of CALPUFF (Version 5.8.4, Level 130731). We disagree with the commenters that a new CALPUFF version should be used for the BART determinations. We relied on version 5.8 of CALPUFF because it is the version approved by EPA through a public notice-and-comment rulemaking, in accordance with the Guidelines (40 CFR part 51, appendix W, section 6.2.1.e). Later versions of CALPUFF are not approved by EPA for regulatory purposes, and we do not agree that the changes made to this most recent version of CALPUFF were simple model updates to address bugs. A full evaluation of a new model such as CALPUFF version 6.4 is needed before it should be used for regulatory purposes as errors that are not immediately apparent can be introduced along with new model features.

In response to comments, EPA performed additional modeling analysis to assess the combined benefit of SCR when applied to each of the two BART units at the Hunter facility. We did the same for the Huntington facility. These modeling results are shown in Tables 6 and 7 earlier in this document. Otherwise, we did not receive any comments that convinced us to alter our CALPUFF modeling analysis, and the comments we received do not justify a change in our BART determinations or our evaluation of the State's BART Alternative. We discuss these and other modeling comments in detail in our RTC document.

I. Consideration of Existing Controls

Comment: Several commenters asserted that EPA did not properly take into account the existing pollution control technology in use at the Hunter and Huntington BART units, as required by CAA section 169A(g)(2) and the BART Guidelines. Two of these commenters alleged that EPA was required to consider updated combustion controls, which were installed to comply with Utah's regional haze SIP. The commenters said EPA improperly used 2001–2003 emissions data to establish the baseline emissions for the Utah BART Units and that this is neither realistic nor provides the anticipated emissions as required by the BART Guidelines. The commenters asserted that had EPA relied on more recent emissions data, which reflect the NO_X reductions achieved by some of these newly installed controls, the cost-effectiveness values for SCR would have been higher, while the visibility improvement associated with SCR would have been lower.

Commenters pointed to an 8th Circuit court decision on EPA's final action on the North Dakota regional haze SIP where the Court found that EPA had failed to properly consider the existing pollution control technology at the Coal Creek Station. Commenters also asserted that in other EPA regional haze actions, EPA had adjusted baseline emissions to account for recently installed controls, such as EPA's final actions on the Arizona and Colorado regional haze SIPs, and settlement agreement with EPA Region 8 for the Deseret Bonanza plant. This commenter argued that because EPA had adjusted baseline emissions for some Arizona and Colorado EGUs to account for controls recently installed to satisfy consent decrees obligations or CAA requirements unrelated to regional haze, EPA was required to do so for Utah's EGUs as well.

Two final commenters submitted supportive comments regarding the need for using a standard baseline period to provide for greater national consistency. One of these commenters noted examples where EPA has evaluated NO_X BART based on a baseline period from before the installation of the pollution controls, for the Navajo regional haze plan and the Wyoming regional haze plan.

Response: We disagree with comments that EPA failed to consider or unreasonably considered the existing pollution control technology at the Hunter and Huntington BART units. One of the statutory factors EPA is to consider for BART is "any existing pollution control technology in use at the source." 42 U.S.C. 7491(g)(2). The CAA and the BART Guidelines do not specify how states or EPA must "take into consideration" this factor. Nor did the Eighth Circuit Court of Appeals specify how existing controls must be taken into account; instead it only examined the meaning of the word "any," holding that EPA misinterpreted the term. *North Dakota* v. *U.S. EPA,* 730 F.3d 750, 762–64 (8th Cir. 2013). The Court did not examine the meaning of the phrase "take into consideration." *See id.* As the statute is silent on how to take into consideration existing controls, under *Chevron U.S.A.* v. *NRDC,* 467 U.S. 837, 843–44 (1984), this silence creates a gap for EPA to fill. As next summarized and detailed in our RTC document, we are reasonably considering existing controls in several ways.

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[138] 80 FR 45340, 45350 (July 29, 2015).

[139] *Id.*

First, the BART Guidelines state that existing pollution control technology in use at the source affects the availability of control options and their impacts. 40 CFR part 51, appendix Y, at IV.A. The Guidelines go on to explain that "[f]or emission units subject to a BART review, there will often be control measures or devices already in place. For such emission units, it is important to include control options that involve improvements to existing controls and not to limit the control options only to those measures that involve a complete replacement of control devices." 40 CFR part 51, appendix Y, at IV.D.1.6. We have followed this recommendation. We find that the existing combustion controls, LNB/SOFA, cannot be reasonably upgraded, and we are not considering a control option that involves their complete replacement. The post-combustion control options, SNCR and SCR, by their nature can operate independently of combustion controls and without changes to the combustion controls, another way in which we considered the existing controls when evaluating SNCR and SCR.

Consistent with the Guidelines' statement that existing pollution control equipment in use at the source affects the impacts of the control options, we used the sources' current NO_X emission rates when we evaluated the size, design, and reagent/catalyst cost of SNCR and SCR. For example, in the case of Hunter Unit 1, we did not use the baseline emission rate of 0.40 lb/MMBtu, but rather the current emission rate of 0.21 lb/MMBtu that appropriately reflects the installation of LNB/SOFA. Due to the lower NO_X emission rate, the size of the SNCR and SCR systems and the amount of reagent/catalyst necessary to operate them are lower than if we had simply assumed the baseline emission rate. This is a reasonable way in which to consider existing pollution control technology.

As discussed in our Wyoming action and in additional detail in our RTC document for this action, baseline emissions should be "a realistic depiction of anticipated annual emissions" *before* the installation of BART. 40 CFR part 51, appendix Y, at IV.D.4.d. Because the LNB/OFA were installed pursuant to Utah's proposed BART determination, we used the period 2001–2003, prior to the installation of LNB/OFA at the Hunter and Huntington BART units, for baseline emissions, which in turn we used to evaluate the cost-effectiveness and visibility of control options. As a result, the existing LNB/OFA were not included in the baseline. According to the commenter, this skewed EPA's analysis.

We disagree. Because we have also considered the existing controls in our final BART determination by examining the cost-effectiveness and visibility benefit of SNCR and SCR relative to the existing LNB/SOFA as well as in tandem with LNB/SOFA, we have avoided any possibility that exclusion of the LNB/OFA from the baseline could result in an unreasonable BART selection. The cost-effectiveness values of SCR and SNCR relative to the existing LNB/SOFA are presented in the per-unit tables for Hunter and Huntington (Tables 2–5) under "Incremental cost-effectiveness." In other words, the cost-effectiveness value for SCR alone (assuming the existing LNB/SOFA) is essentially the same as the incremental cost-effectiveness of SCR + LNB/SOFA as compared to LNB/SOFA that is presented in the tables. As can be seen, the incremental cost-effectiveness values of SCR + LNB/SOFA relative to LNB/SOFA are, for all four units, somewhat lower than the incremental cost-effectiveness of SCR relative to SNCR. As explained in the section giving the rationale for our final action, we find the incremental cost-effectiveness of SCR to be reasonable relative to SNCR; therefore it is also reasonable relative to the existing LNB/SOFA.

Another way to make the same point is to, for the sake of argument, accept (which we do not) commenter's position that the baseline should reflect the LNB/SOFA. In that case, the values in the tables for the incremental cost-effectiveness of SCR + LNB/SOFA relative to LNB/SOFA can serve as a proxy for the average cost-effectiveness of SCR (assuming LNB/SOFA in the baseline). As shown by our comparisons, the incremental cost-effectiveness of SCR + LNB/SOFA is generally reasonable given the visibility benefits. This in turn shows that, even accepting for the sake of argument that LNB/SOFA should be reflected in the baseline, the average cost-effectiveness of SCR remains reasonable. Similar considerations apply to the incremental visibility benefits of SCR + LNB/SOFA relative to LNB/SOFA, which can be used as a proxy for the visibility benefits of SCR alone assuming that LNB/SOFA are reflected in the baseline. As shown by our comparisons, the incremental visibility benefits of SCR + LNB/SOFA relative to SNCR + LNB/SOFA are substantial and justify the costs of SCR. Since the incremental visibility benefits of SCR + LNB/SOFA relative to LNB/SOFA are necessarily larger than the incremental benefits relative to SNCR + LNB/SOFA, the incremental visibility benefits of SCR + LNB/SOFA relative to LNB/SOFA will also justify the costs of SCR. This in turn shows that even if we accepted the commenter's position—which we do not—the visibility benefits of SCR would justify its selection. For our detailed responses, please see our RTC document.

Finally, we acknowledge the supportive comments from two commenters on this issue and agree with many of the points that were made, for reasons explained elsewhere in this document and in our RTC document.

J. PM_{10} BART

Comment: We received several minor comments on Utah's PM_{10} BART determinations. One commenter in particular asserted that Utah underestimated the control effectiveness of baghouses, which should be able to achieve a limit of 0.010 lb/MMBtu or even lower.

Response: EPA agrees that baghouses have very high PM control efficiency capabilities. However, due to the low contribution of direct PM emissions from point sources such as Hunter Units 1 and 2 and Huntington Units 1 and 2 [140] to visibility impairment and, consequently, the low anticipated visibility benefits from small PM reductions, lowering the emission limit to 0.010 is unlikely to result in any meaningful visibility improvement. We agree with Utah that the existing PM_{10} emission limit adopted for these sources in Section IX, Part H.22 of Utah's SIP satisfies BART for these units. We are finalizing our approval of Utah's PM_{10} BART determination at Hunter Units 1 and 2 and Huntington Units 1 and 2. We find that an emission limit of 0.015 lb/MMBtu represents what can be continuously achieved with a properly operated baghouse on these units. The fabric filters (*i.e.*, baghouses) at Hunter and Huntington are all new since they were installed after 2008. Recent PSD BACT limits for coal-fired EGUs with new baghouses have typically ranged from 0.01 to 0.015 lb/MMBtu using Method 5.

In addition, we note that the latest revision to the EGU New Source Performance Standards (NSPS) requires modified units to meet a PM limit of 0.015 lb/MMBtu.[141] Also, the EGU MATS rule set a PM emissions standard of 0.03 lb/MMBtu as MACT for existing EGUs, and the BART Guidelines provide that, "unless there are new technologies subsequent to the MACT standards which would lead to cost-effective increases in the level of control, you may rely on the MACT standards for purposes of BART."[142] Therefore, we are finalizing our proposed approval of Utah's BART determination for PM_{10} at Hunter Units 1 and 2 and Huntington Units 1 and 2.

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[140] See Western Regional Air Partnership Regional Haze Rule Reasonable Progress Summary Report, Air Resource Specialist, Inc., State and Class I Area Summaries, Appendix p. 6–29, Table 6.13–19 (June 28, 2013). Available in the docket and at *http://www.wrapair2.org/RHRPR.aspx*.

[141] 77 FR 9450 (Feb. 16, 2012) (codified at 40 CFR 60.42Da).

K. Environmental Justice

Comment: One commenter requested that EPA's FIP address any disproportionately high and adverse human health, economic, and environmental impacts on minority and low-income communities in Utah due to the regional haze plan. The commenter noted that this may be accomplished consistent with federal Executive Order 12898, which establishes environmental justice policy. The commenter also noted that societal costs such as general public health costs associated with poor air quality should be considered in the environmental justice analysis.

Response: In making a final determination in this case, EPA considered Executive Order 12898, which establishes federal executive policy on environmental justice. This Executive Order directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. The installation of SCR at the two facilities will ensure greater emissions reductions of NO_X resulting in overall increases in the level of environmental protection for all affected populations.

EPA disagrees with the comment that societal costs such as general public health costs associated with poor air quality should be considered in the environmental justice analysis for this action. As addressed elsewhere in our RTC document, neither section 169A of the CAA, nor the BART Guidelines, require the BART analysis to include or quantify benefits to health, as health impacts are appropriately addressed under other CAA programs. Moreover, an analysis of societal costs is unlikely to alter the impact relating to environmental justice concerns because the final rule will result in greater protection for all affected populations as a result of the installation of the most stringent control technology available for NO_X.

III. Final Action

For the reasons discussed more fully in sections I and II and detailed in our proposal and its accompanying supporting materials, in this action, we are partially approving and partially disapproving revisions to the Utah SIP submitted by the State of Utah on June 4, 2015. We are taking no action on the Utah SIP submittal of October 20, 2015.

Section 110(k)(3) of the Act addresses the situation in which an entire submittal, or a separable portion of a submittal, meets all applicable requirements of the Act. In the case where a separable portion of the submittal meets all the applicable requirements, partial approval may be used to approve that part of the submittal and disapprove the remainder. Since the portions of the regional haze SIP submittal we are approving are separable from the portions we are disapproving as explained earlier, each approved PM_{10} BART determination for a particular pollutant for a given source will have an enforceable date of five years from the date of EPA's approval.

Under section 110(k)(4) of the Act, EPA may approve a submittal based on a commitment of the State to adopt specific enforceable measures no later than one year after the date of approval of the submittal. We are conditionally approving the State's recordkeeping requirements for the PM BART emission limitations based on Utah's commitment to adopt and submit certain measures to address the deficiencies in the recordkeeping requirements. If the State fails to adopt and submit these measures within one year of this action, our conditional approval will be treated as a disapproval.

Under section 110(c)(1)(B) of the Act, within two years of disapproving a required submittal in whole or in part, EPA must promulgate a FIP to address the deficiencies, unless the State corrects the deficiencies through a submittal and EPA approves the submittal before we promulgate a FIP. As a result of our prior disapproval of Utah's PM and NO_X BART submittals in 2012, there was a pending obligation for EPA to promulgate a FIP for PM and NO_X BART. In this action, we are promulgating a FIP for NO_X BART. Because we are approving Utah's revised PM BART submittal, which corrects the previous deficiencies in the original PM BART submittal, there is no longer an obligation for EPA to promulgate a FIP for PM BART. Thus, EPA has discharged its FIP obligations with respect to PM and NO_X BART for the State of Utah.

A. Final Partial Approval

1. We are approving these elements of the State's SIP submittals, which rely on elements from prior approvals:[143]

- BART determinations and emission limits for PM_{10} at Hunter Units 1 and 2 and Huntington Units 1 and 2.
- Monitoring, recordkeeping, and reporting requirements for units subject to the PM_{10} emission limits, including conditional approval of the recordkeeping requirements for the PM_{10} emission limits.

B. Final Partial Disapproval and Federal Implementation Plan

1. We are disapproving these aspects of the State's June 4, 2015 SIP submittal:

- NO_X BART Alternative that includes NO_X, and SO_2 emission reductions from Hunter Units 1 through 3, Huntington 1 and 2, and Carbon Units 1 and 2, and PM_{10} emission reductions from Carbon Units 1 and 2.
- Monitoring, recordkeeping and reporting requirements for units subject to the BART Alternative.

2. We are promulgating a FIP to address the deficiencies in the Utah regional haze SIP. The FIP includes the following elements:

- NO_X BART determinations and limits for Hunter Units 1 and 2, Huntington Units 1 and 2.
- Monitoring, recordkeeping, and reporting requirements applicable to Hunter Units 1 and 2, and Huntington Units 1 and 2.

C. No Action

1. We are taking no action on the State's October 20, 2015 SIP submittal which includes the following:

- The enforceable commitments to revise, at a minimum, SIP Section XX.D.3.c and State rule R307–150 by March 2018.

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[142] 40 CFR part 51, appendix Y, section IV.C. While the Supreme Court reversed the D.C. Circuit's judgment on the MATS rule, the Supreme Court did so based on EPA's approach to the "appropriate and necessary" finding, not EPA's determination of MACT for EGUs. *Michigan* v. *EPA,* 135 S. Ct. 2699 (2015).

[143] As necessary for our approval, we are filling gaps in the 2015 Utah regional haze RH SIP submittals with the following already-approved sections from the 2011 Utah RH SIP: Section XX.B.8, Figures 1 and 2, Affected Class I Areas, pp. 8–9; Section XX.D.6.b, Table 3, BART-Eligible Sources in Utah, p. 21; Section. XX.D.6.c, Sources Subject to BART, pp. 21–23.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Utah Administrative Code discussed in section III, Final Action of this preamble. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is exempt from review by the Office of Management and Budget (OMB) because this final rule applies to only two facilities containing four BART units. It is therefore not a rule of general applicability.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act (PRA).[144] Because this final rule applies to just two facilities, the PRA does not apply.

C. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

EPA is partially disapproving the State's SIP submittal and promulgating a FIP that consists of imposing federal controls to meet the BART requirement for emissions on four specific BART units at two facilities in Utah. The net result of this action is that EPA is requiring direct emission controls on selected units at only two sources, and those sources are large electric generating plants that are not owned by small entities, and therefore the owners are not a small entities under the RFA.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

EPA has determined that Title II of the UMRA does not apply to this rule. In 2 U.S.C. 1502(1) all terms in Title II of UMRA have the meanings set forth in 2 U.S.C. 658, which further provides that the terms "regulation" and "rule" have the meanings set forth in 5 U.S.C. 601(2). Under 5 U.S.C. 601(2), "the term 'rule' does not include a rule of particular applicability relating to . . . facilities." Because this rule is a rule of particular applicability relating to all four BART units at the Hunter and Huntington plants, EPA has determined that it is not a "rule" for the purposes of Title II of the UMRA. The private sector expenditures that result from promulgating a FIP include BART controls for all four units at the Hunter and Huntington plants are $58.6 million[145] per year. Additionally, we do not foresee significant costs (if any) for state and local governments. Thus, because the annual expenditures associated with promulgating a FIP are less than the threshold of $100 million in any one year, this final rule is not subject to the requirements of sections 202 or 205 of UMRA. This final rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. Moreover, "regulation" or "rule," is defined in Executive Order 12866 as "an agency statement of general applicability and future effect." E.O. 12866 does not define "statement of general applicability," but this term commonly refers to statements that apply to groups or classes, as opposed to statements, which apply only to named entities. The FIP therefore is not a rule of general applicability because its requirements apply and are tailored to only the Hunter and Huntington plants, which are individually identified facilities. Thus, it is not a "rule" or "regulation" within the meaning of E.O. 12866. However, as this action will limit emissions of NO_X, it will have a beneficial effect on children's health by reducing air pollution.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained within the docket in a document entitled "Environmental Justice Analysis, November 2015." This final rule will result in overall emission reductions for NO_X, and PM_{10} and therefore an increase in the level of environmental protection for all affected populations.

K. Congressional Review Act

This action is not subject to the CRA because this is a rule of particular applicability. Additionally, this action is not a "major rule" as defined by 5 U.S.C. 804(2).

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[144] 44 U.S.C. 3501 *et seq.*

[145] Andover Technology Partners, *Cost of NO_X BART Controls on Utah EGUs*, to EC/R, Inc. (May 13, 2016). Andover Technology Partners is a subcontractor to EC/R Incorporated.

L. Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 2016. Pursuant to CAA section 307(d)(1)(B), this action is subject to the requirements of CAA section 307(d) as it promulgates a FIP under CAA section 110(c). Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See CAA section 307(b)(2).

Authority: 42 U.S.C. 7401 *et seq.*

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Sulfur oxides.

Dated: June 1, 2016.

Gina McCarthy,

Administrator.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart TT—Utah

■ 2. Section 52.2320 is amended by:

■ a. In the table in paragraph (c), under the heading "R307–110. General Requirements: State Implementation Plan" revising the entry "R307–110–17."

■ b. In the table in paragraph (e), under the heading "XVII. Visibility Protection" adding in numerical order the entry "Section XX.D.6. Best Available Retrofit Technology (BART) Assessment for NO_X and PM".

The revision and addition read as follows:

§ 52.2320 Identification of plan.

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(c) * * *

Rule No.	Rule title	State effective date	Final rule citation, date	Comments
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R307–110. General Requirements: State Implementation Plan				
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R307–110–17.	Section IX. Control Measures for Area and Point Sources, Part H, Emissions Limits.	6/4/2015	[Insert **Federal Register** citation] 7/5/2016.	Except for Section IX.H.21.e. which is conditionally approved through one year from [Insert date of publication in the **Federal Register**], IX.H.21.g., Sections of IX.H.21 that reference and apply to the source specific emission limitations disapproved in Section IX.H.22, and Sections IX.H.22.a.ii-iii, IX.H.22.b.ii, and IX.H.22.c.
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Rule title	State effective date	Final rule citation, date	Comments
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XVII. Visibility Protection			

Rule title	State effective date	Final rule citation, date	Comments
* * *	* *	* *	* *
Section XX.D.6. Best Available Retrofit Technology (BART) Assessment for NO_X and PM.	6/4/2015	[Insert **Federal Register** citation] 7/5/2016.	Except for XX.D.6.a the phrase "and BART for NO_X through alternative measures under 40 CFR 51.308(e)(2)"; XX.D.6.c; XX.D.6.d the phrase "NO_X and" in the first sentence, the entire last sentence in the introductory paragraph, all SO_2 and NO_X provisions and the word "Permitted" in the "Utah Permitted Limits" column in Table 5, "Hunter 3" and the Hunter limits, and all provisions in the "Presumptive BART Rates" column in Table 5; XX.D.6.e the phrase ", and pursuant to 51.308(e)(2)(E)(3) all alternative measures must take place within the first planning period", the rows beginning with "Hunter 3", "Carbon 1" and "Carbon 2" in Table 6, and the entire paragraph immediately following Table 6.
* * *	* *	* *	* *

■ 3. Section 52.2336 is added to read as follows:

§ 52.2336 Federal implementation plan for regional haze.

(a) *Applicability.* (1) This section applies to each owner and operator of the following emissions units in the State of Utah:

(i) PacifiCorp Hunter Plant Units 1 and 2; and

(ii) PacifiCorp Huntington Plant Units 1 and 2.

(2) [Reserved]

(b) *Definitions.* Terms not defined in this paragraph (b) shall have the meaning given them in the Clean Air Act or EPA's regulations implementing the Clean Air Act. For purposes of this section:

(1) *BART* means Best Available Retrofit Technology.

(2) *BART unit* means any unit subject to a Regional Haze emission limit in Table 1 of this section.

(3) *Continuous emission monitoring system* or *CEMS* means the equipment required by this section to sample, analyze, measure, and provide, by means of readings recorded at least once every 15 minutes (using an automated data acquisition and handling system (DAHS)), a permanent record of NO_X emissions, diluent, or stack gas volumetric flow rate.

(4) *FIP* means Federal Implementation Plan.

(5) The term *lb/MMBtu* means pounds per million British thermal units of heat input to the fuel-burning unit.

(6) NO_X means nitrogen oxides.

(7) *Operating day* means a 24-hour period between 12 midnight and the following midnight during which any fuel is combusted at any time in the BART unit. It is not necessary for fuel to be combusted for the entire 24-hour period.

(8) The *owner/operator* means any person who owns or who operates, controls, or supervises a unit identified in paragraph (a) of this section.

(9) *Unit* means any of the units identified in paragraph (a) of this section.

(c) *Emission limitations.* (1) The owners/operators of emission units subject to this section shall not emit, or cause to be emitted, NO_X in excess of the following limitations:

TABLE 1 TO § 52.2336—EMISSION LIMITATIONS FOR BART UNITS

Source name/BART unit	NO_X Emission limitation—lb/MMBtu (30-day rolling average)
PacifiCorp Hunter Plant/Unit 1[1]	0.07
PacifiCorp Hunter Plant/Unit 2[1]	0.07
PacifiCorp Huntington Plant/Unit 1[1]	0.07
PacifiCorp Huntington Plant/Unit 2[1]	0.07

[1] The owners and operators of PacifiCorp Hunter Units 1 and 2 and Huntington Units 1 and 2, shall comply with the NO_X emission limit for BART of 0.07 lb/MMBtu and other requirements of this section by August 4, 2021.

(2) These emission limitations shall apply at all times, including startups, shutdowns, emergencies, and malfunctions.

(d) *Compliance date.* (1) The owners and operators of PacifiCorp Hunter Units 1 and 2 shall comply with the NO_X emission limitation of 0.07 lb/MMBtu and other requirements of this section by August 4, 2021. The owners and operators of PacifiCorp Huntington Units 1 and 2 shall comply with the NO_X emission limitation of 0.07 lb/MMBtu and other requirements of this section by August 4, 2021.

(2) [Reserved]

(e) *Compliance determinations for* NO_X. (1) For all BART units:

(i) *CEMS.* At all times after the earliest compliance date specified in paragraph (d) of this section, the owner/operator of each unit shall maintain, calibrate, and operate a CEMS, in full compliance with the requirements found at 40 CFR part 75, to accurately measure NO_X, diluent, and stack gas volumetric flow rate from each unit. The CEMS shall be used to determine compliance with the emission limitations in paragraph (c) of this section for each unit.

(ii) *Method.* (A) For any hour in which fuel is combusted in a unit, the owner/operator of each unit shall calculate the hourly average NO_X emission rate in lb/MMBtu at the CEMS in accordance with the requirements of 40 CFR part 75. At the end of each operating day, the owner/operator shall calculate and record a new 30-day rolling average emission rate in lb/MMBtu from the arithmetic average of all valid hourly emission rates from the CEMS for the current operating day and the previous 29 successive operating days.

(B) An hourly average NO_X emission rate in lb/MMBtu is valid only if the minimum number of data points, as specified in 40 CFR part 75, is acquired by both the pollutant concentration monitor (NO_X) and the diluent monitor (O_2 or CO_2).

(C) Data reported to meet the requirements of this section shall not include data substituted using the missing data substitution procedures of subpart D of 40 CFR part 75, nor shall the data have been bias adjusted according to the procedures of 40 CFR part 75.

(2) [Reserved]

(f) *Recordkeeping.* The owner/operator shall maintain the following records for at least five years:

(1) All CEMS data, including the date, place, and time of sampling or measurement; parameters sampled or measured; and results.

(2) Records of quality assurance and quality control activities for emissions measuring systems including, but not limited to, any records required by 40 CFR part 75.

(3) Records of all major maintenance activities conducted on emission units, air pollution control equipment, and CEMS.

(4) Any other CEMS records required by 40 CFR part 75.

(g) *Reporting.* All reports under this section shall be submitted to the Director, Office of Enforcement, Compliance and Environmental Justice, U.S. Environmental Protection Agency, Region 8, Mail Code 8ENF–AT, 1595 Wynkoop Street, Denver, Colorado 80202–1129.

(1) The owner/operator of each unit shall submit quarterly excess emissions reports for NO_X BART units no later than the 30th day following the end of each calendar quarter. Excess emissions means emissions that exceed the emissions limits specified in paragraph (c) of this section. The reports shall include the magnitude, date(s), and duration of each period of excess emissions, specific identification of each period of excess emissions that occurs during startups, shutdowns, and malfunctions of the unit, the nature and cause of any malfunction (if known), and the corrective action taken or preventative measures adopted.

(2) The owner/operator of each unit shall submit quarterly CEMS performance reports, to include dates and duration of each period during which the CEMS was inoperative (except for zero and span adjustments and calibration checks), reason(s) why the CEMS was inoperative and steps taken to prevent recurrence, and any CEMS repairs or adjustments. The owner/operator of each unit shall also submit results of any CEMS performance tests required by 40 CFR part 75.

(3) When no excess emissions have occurred or the CEMS has not been inoperative, repaired, or adjusted during the reporting period, such information shall be stated in the quarterly reports required by paragraphs (g)(1) and (2) of this section.

(h) *Notifications.* (1) The owner/operator shall promptly submit notification of commencement of construction of any equipment which is being constructed to comply with the NO_X emission limits in paragraph (c) of this section.

(2) The owner/operator shall promptly submit semi-annual progress reports on construction of any such equipment.

(3) The owner/operator shall promptly submit notification of initial startup of any such equipment.

(i) *Equipment operation.* At all times, the owner/operator shall maintain each unit, including associated air pollution control equipment, in a manner consistent with good air pollution control practices for minimizing emissions.

(j) *Credible evidence.* Nothing in this section shall preclude the use, including the exclusive use, of any credible evidence or information, relevant to whether a source would have been in compliance with requirements of this section if the appropriate performance or compliance test procedures or method had been performed.

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